

US3172360 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:05:52

All time stamps listed in this document are displayed in GMT

US3172360

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

---

Participant ID

US3172360

---

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

---

---

US3172360

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	27 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
------------	------

US3172360

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3172360

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Date of Informed Consent (dd MMM yyyy) 27 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 type="radio"/>
Amendment 3	<input checked="" 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

US3172360

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

---

Did the participant meet all eligibility criteria?

Yes ☒  
No ☐

---

US3172360

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Were any significant conditions reported?

Yes ☒

No ☐

US3172360

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	MIGRAINE
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3172360

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	BILATERAL MYOPIA / STIGMATISM
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172360

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	MODERATE ASTHMA
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Start Year (derived)	1966
Stop Month and Year (derived)	
Stop Year (derived)	

US3172360

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	PREDIABETES
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)	_____

US3172360

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	OVARIAN CYSTS
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3172360

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

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

US3172360

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172360

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

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

US3172360

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

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



US3172360

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

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

US3172360

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

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

US3172360

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

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

US3172360

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	CURRENT TOBACCO USER
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	
Stop Year (derived)	

US3172360

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	ALCOHOL CONSUMPTION
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172360

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	CAFFEINE CONSUMPTION
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172360

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Condition	PERICARDIAL SAC FIBROSIS
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3172360

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 09:25
Height (xxx.x)	161.0 cm
Weight (xxx.x)	081.3 kg
BMI (xxx.x)	31.36453 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)	



US3172360

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

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.*

US3172360

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Date of assessment (dd MMM yyyy) 27 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) \_\_\_\_\_  
Date of last menstruation unknown False

US3172360

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 27 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3172360

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify** DISABLED

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

**No Risk Identified** False

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

US3172360

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

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

US3172360

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	27 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
------------	--------

US3172360

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 145121

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 ☒

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Height	ND - Not Done
Weight	ND - Not Done



US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

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)	27 AUG 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 09:35
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

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)	27 AUG 2020
Time of assessment (00:00-23:59)	12:28 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 12:28
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3172360

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3172360

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3172360

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 11:58 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 11:58

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

US3172360

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 27 AUG 2020

Collection time (00:00-23:59) 11:32 (24 HR)

Collection date and time (derived) 27 AUG 2020 11:32

US3172360

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:09	27 AUG 2020 11:09
Nasopharyngeal Swab 2	No		

US3172360

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:44

PC Open Date & Time

27 AUG 2020 12:18

PC Close Date & Time

27 AUG 2020 14:48

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	27 AUG 2020 17:18
PC Open Date & Time	27 AUG 2020 15:43
PC Close Date & Time	28 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:52

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 16:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:52

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 17:30

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:52

---

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 16:58

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:52

---

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 17:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:52

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °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

01 SEP 2020 17:07

---

PC Open Date & Time

01 SEP 2020 12:00

---

PC Close Date & Time

02 SEP 2020 11:59

---

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

02 SEP 2020 15:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59



US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:46

PC Open Date & Time

27 AUG 2020 12:18

PC Close Date & Time

27 AUG 2020 14:48

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**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

27 AUG 2020 17:18

PC Open Date & Time

27 AUG 2020 15:43

PC Close Date & Time

28 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:52

**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

28 AUG 2020 16:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:52

**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

29 AUG 2020 17:30

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:52

**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

30 AUG 2020 16:59

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:52

**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

31 AUG 2020 17:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:52

**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

01 SEP 2020 17:07

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**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

02 SEP 2020 15:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59



US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

**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 ☐

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 12:46
PC Open Date & Time	27 AUG 2020 12:18
PC Close Date & Time	27 AUG 2020 14:48

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**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 ☐

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 17:19
PC Open Date & Time	27 AUG 2020 15:43
PC Close Date & Time	28 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:52

**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 ☒

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:52

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 16:34
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:52

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

62 of 1854

EAB) (1725)

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:52

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 17:31
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59



US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:52

**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

64 of 1854

EAB) (1725)

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:52

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 16:59
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:52

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

66 of 1854

EAB) (1725)

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:52

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 17:15
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:52

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 ☒

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:52

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 17:08
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:52

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  
EAB) (1725)

70 of 1854

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:52

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 15:46
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59



US3172360

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 SEP 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3172360

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3172360

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

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*

US3172360

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

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)	22 SEP 2020
Time of assessment (00:00-23:59)	07:57 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 07:57
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3172360

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3172360

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 22 SEP 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

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?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3172360

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

09:51 (24 HR)

Collection date and time (derived)

22 SEP 2020 09:51

US3172360

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:36	22 SEP 2020 09:36
Nasopharyngeal Swab 2	No		

US3172360

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 SEP 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3172360

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 06 OCT 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3172360

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3172360

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 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
------------	--------

US3172360

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:28
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172360

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

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.*



US3172360

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

11:58 (24 HR)

Collection date and time (derived)

22 OCT 2020 11:58

US3172360

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:49

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 OCT 2020 00:29:36
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3172360

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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

03 NOV 2020 01:39:35

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3172360

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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

10 NOV 2020 01:03:03

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 89

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

No ☒

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 00:33:49

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 02:05:30
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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

05 DEC 2020 00:02:39

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59



US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 00:30:50

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☒

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 00:02:37

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☒

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

26 DEC 2020 02:12:21

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 JAN 2021 00:02:00
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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

09 JAN 2021 00:03:51

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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

16 JAN 2021 00:38:49

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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

23 JAN 2021 00:01:49

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 01:34:15

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59



US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 166

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

No ☒

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

07 FEB 2021 20:31:46

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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

13 FEB 2021 00:04:25

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 00:13:46

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 FEB 2021 00:01:29
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 MAR 2021 00:01:28
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

<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	13 MAR 2021 20:25:38
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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

23 MAR 2021 10:12:50

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 02:02:53

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59



US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 01:57:14

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 01:03:57

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 00:46:39

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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

24 APR 2021 00:50:07

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 00:07:06

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

22 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 MAY 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

29 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 JUN 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUN 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

17 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

21 JUL 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

31 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

04 AUG 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 AUG 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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 <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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 AUG 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

21 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

25 AUG 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 376

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

11 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 SEP 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 397

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 SEP 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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="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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 NOV 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

20 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 NOV 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 460

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

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

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

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

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

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

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

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



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 DEC 2021 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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="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"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	05 MAR 2022 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	09 MAR 2022 23:59
---	-------------------

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

12 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

16 MAR 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

19 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 MAR 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 APR 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 MAY 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 MAY 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 642

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐ Yes ☐

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

11 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 JUN 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

02 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

06 JUL 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2022 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
---	-------------------

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

10 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 SEP 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 SEP 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**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 ☐

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

08 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

12 OCT 2022 23:59

---

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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 <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"/>

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59

US3172360

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

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"/>



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3172360

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:05:52

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 06:11:41

US3172360

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 NOV 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3172360

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 DEC 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3172360

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3172360

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3172360

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 14:00:41

Generated On: 11 Aug 2021 22:05:52

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

MISSED OPEN LABEL

If Contact Not Made, please provide Comments

US3172360

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:00:41

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	23 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3172360

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 MAR 2021
Time of assessment (00:00-23:59)	08:25 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 08:25
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172360

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

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.*

US3172360

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

09:53 (24 HR)

Collection date and time (derived)

23 MAR 2021 09:53

US3172360

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 APR 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3172360

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3172360**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

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*

**US3172360**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172360

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:52

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"/>

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 28 JAN 2021

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☒

Folder OID UNBLND\_DECIDE

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

Date of updated informed consent ( <i>dd MMM yyyy</i> )	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	28 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	



US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	28 JAN 2021
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 08:52
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	28 JAN 2021
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 11:15
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 28 JAN 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 28 JAN 2021

What was the treatment time? (00:00-23:59) 10:45 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 10:45

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

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

10:35 (24 HR)

Collection date and time (derived)

28 JAN 2021 10:35

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00 - 23:59)

10:37

Collection Date and Time (derived)

28 JAN 2021 10:37

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3172360

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3172360

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:35:48

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3172360

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 14:00:41

Generated On: 11 Aug 2021 22:05:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	26 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
------------	-------

US3172360

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 14:00:41

Generated On: 11 Aug 2021 22:05:52

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)	26 FEB 2021
Time of assessment (00:00-23:59)	09:06 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 09:06
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3172360

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 14:00:41

Generated On: 11 Aug 2021 22:05:52

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	

US3172360

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 14:00:41

Generated On: 11 Aug 2021 22:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3172360

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 03 Mar 2021 14:00:41

Generated On: 11 Aug 2021 22:05:52

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 26 FEB 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3172360

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

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

SUBJECT DID NOT DOSE ON DAY 29 VISIT, THEY RECEIVED ONE DOSE OF MRNA IN PART A AND SECOND DOSE ON DECISION VISIT.

What was the study treatment? (Unblinded) \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

What was the treatment time? (00:00-23:59) \_\_\_\_\_

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_



US3172360

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:00:41

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172360

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

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

MISSED

If Contact Not Made, please provide Comments

US3172360

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:33:20

Generated On: 11 Aug 2021 22:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3172360**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

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 \_\_\_\_\_

US3172360

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3172360

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

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.*

**US3172360**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3172360

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

AEID	
Adverse event	PSORIASIS FLARE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

328 of 1854

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

---

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

Yes ☒

No ☐

---

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

---

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Name of Medication XANAX

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 1

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)

331 of 1854

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Name of Medication OLZAPINE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 30

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)

333 of 1854

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Name of Medication DEPAKOTE

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR

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 ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

335 of 1854



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 90

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)

337 of 1854

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Name of Medication EXCEDRIN - (ACETAMINOPHEN  
250 MG) (ASPIRIN 250 MG)  
(CAFFEINE 65 MG)

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE

Dose per administration 1

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)

339 of 1854

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE

Dose per administration 250

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

341 of 1854

EAB) (1725)

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

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

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE

Dose per administration 250

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

343 of 1854

EAB) (1725)



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

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

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Name of Medication CAFFEINE

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE

Dose per administration 65

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)

345 of 1854

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

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

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

Name of Medication CLOBETAZOL CREAM

Prophylaxis Yes ☐  
No ☒

Indication PSORIASIS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

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

347 of 1854

EAB) (1725)

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 17 Feb 2021 13:35:39

Generated On: 11 Aug 2021 22:05:52

	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)	25 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172360

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3172360

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 17 Feb 2021 13:35:40

Generated On: 11 Aug 2021 22:05:52

Date of dosing discontinuation (dd MMM yyyy) 22 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify A/E #1

US3172360

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:05:52

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 ☐



Audit

US3172360 (Prod: Suncoast Research Group LLC - ERN-PPDS)

**US3172360**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:05:52**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'US3172360'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:45:23

**US3172360**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:09:04

US3172360

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:45:24

**US3172360**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:09:04

**US3172360**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'SCRN'	System	27 Aug 2020 16:09:04

US3172360

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:45:25

**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '54'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46



**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'YEARS'	System	27 Aug 2020 16:08:46

**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '54'	System	27 Aug 2020 16:09:42

**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Female (F)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

US3172360

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

US3172360

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:52

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'I'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	27 Aug 2020 16:08:46
	(b) (4)	



**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

US3172360

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

**US3172360**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:52**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:46

US3172360

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:09:42

**US3172360**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Aug 2020'	System	27 Aug 2020 16:09:42

**US3172360**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2020'	System	27 Aug 2020 16:09:42



**US3172360**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:05:52**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Amendment 3 (3)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:09:42

US3172360

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:09:42

**US3172360**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:09:42

**US3172360**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:05:52**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:09:42

US3172360

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:09:42

**US3172360**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:05:52**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:45:24

**US3172360**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:05:52**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '1'	System	27 Aug 2020 16:09:42

US3172360

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:08:13



US3172360

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:05:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:41:48

US3172360

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:37:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:37:31
Data point term sent to Coder	System	27 Aug 2020 16:43:08
User entered 'MIGRAINE'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:43:03

**US3172360**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2014'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:43:03

US3172360

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:43:03

**US3172360**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:43:03

**US3172360**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:43:03

**US3172360**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:43:03

**US3172360**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2014'	System	27 Aug 2020 16:43:03



**US3172360**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2014'	System	27 Aug 2020 16:43:03

**US3172360**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	27 Aug 2020 16:43:03

**US3172360**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	27 Aug 2020 16:43:03

US3172360

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:03:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:03:47
Data point term sent to Coder	System	11 Sep 2020 19:01:37
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	11 Sep 2020 19:01:16
User entered 'BILATERAL MYOPIA / STIGMATISM' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Sep 2020 19:01:16
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Myopic astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:16:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:16:50
Data point term sent to Coder	System	27 Aug 2020 16:45:12
User entered 'MYOPIA / STIGMATISM'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:20

**US3172360**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 1975'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:20

**US3172360**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:20

**US3172360**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:20

**US3172360**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:20



**US3172360**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:20

**US3172360**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 1975'	System	27 Aug 2020 16:44:20

**US3172360**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '1975'	System	27 Aug 2020 16:44:20

**US3172360**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	27 Aug 2020 16:44:20

**US3172360**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	27 Aug 2020 16:44:20

US3172360

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:05:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' canceled (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 15:06:10
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 14:33:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:37:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:37:43
Data point term sent to Coder	System	27 Aug 2020 16:45:15
User entered 'MODERATE ASTHMA'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:52

**US3172360**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 1966'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:52

**US3172360**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:52



**US3172360**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	27 Aug 2020 16:44:52
	(b) (4)	

**US3172360**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:52

**US3172360**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:44:52

**US3172360**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 1966'	System	27 Aug 2020 16:44:52

**US3172360**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '1966'	System	27 Aug 2020 16:44:52

**US3172360**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	27 Aug 2020 16:44:52

**US3172360**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	27 Aug 2020 16:44:52

US3172360

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:54:38
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Subject controls pre-diabetes with diet ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Sep 2020 18:54:50
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:01:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Prediabetes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:08:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:08:36
Data point term sent to Coder	System	28 Aug 2020 14:07:57
User entered 'PREDIABETES'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:07:19



**US3172360**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2019'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:07:19

**US3172360**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:07:19

**US3172360**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:07:19

**US3172360**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	28 Aug 2020 14:07:19
	(b) (4)	

**US3172360**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:07:19

**US3172360**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2019'	System	28 Aug 2020 14:07:19

**US3172360**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2019'	System	28 Aug 2020 14:07:19

**US3172360**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 14:07:19



**US3172360**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 14:07:19

US3172360

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 14:11:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 14:11:39
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 14:11:03
User entered 'OVARIAN CYSTS'	Jessie Downs (b) (4)	28 Aug 2020 14:10:19
	(b) (4)	

**US3172360**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 1995'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:10:19

**US3172360**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:10:19

**US3172360**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:10:19

**US3172360**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 1995'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:10:19

**US3172360**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:10:19

**US3172360**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 1995'	System	28 Aug 2020 14:10:19



**US3172360**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '1995'	System	28 Aug 2020 14:10:19

**US3172360**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 1995'	System	28 Aug 2020 14:10:19

**US3172360**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '1995'	System	28 Aug 2020 14:10:19

US3172360

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User closed query 'Per DM CLR: Please specify the location and/or type of ECZEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:54:59
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:53:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:53:43
Data point term sent to Coder	System	11 Sep 2020 20:28:54
Query 'Per DM CLR: Please specify the location and/or type of ECZEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	11 Sep 2020 20:28:51
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	11 Sep 2020 20:28:37
User entered 'ECZEMA torso upper and lower extremity' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Sep 2020 20:28:37
User opened query 'Per DM CLR: Please specify the location and/or type of ECZEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:52:49
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:42:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:42:47
Data point term sent to Coder	System	28 Aug 2020 15:41:42

PRODUCTION RELEASE (v12.003  
EAB) (1725)

435 of 1854

**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition](#)

Audit	User	Time (GMT)
User entered 'ECZEMA'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:41:24

**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2018'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:41:24

**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:41:24

**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:41:24



**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:41:24

**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:41:24

**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2018'	System	28 Aug 2020 15:41:24

**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2018'	System	28 Aug 2020 15:41:24

**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:41:24

**US3172360**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:41:24

US3172360

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:05:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:44:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:44:36
Data point term sent to Coder	System	28 Aug 2020 15:43:51
User entered 'POST-MENOPAUSAL'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:20

**US3172360**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2016'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:20



**US3172360**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:20

**US3172360**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:20

**US3172360**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	28 Aug 2020 15:43:20
	(b) (4)	

**US3172360**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:20

**US3172360**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2016'	System	28 Aug 2020 15:43:20

**US3172360**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2016'	System	28 Aug 2020 15:43:20

**US3172360**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:43:20

**US3172360**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:43:20



US3172360

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:05:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 12:01:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 12:01:27
User closed query 'Per DM CLR: Please specify the location of Psoriasis. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	05 Oct 2020 19:21:22
' (Site from DM).		
Data point term sent to Coder	System	02 Oct 2020 20:30:24
Query 'Per DM CLR: Please specify the location of Psoriasis. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:29:43
' answered with 'Data was updated ' (Site from DM).		
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:29:34
User entered 'UPPER EXTREMITIES PSORIASIS' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:29:34
User opened query 'Per DM CLR: Please specify the location of Psoriasis. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	30 Sep 2020 23:38:49
' (Site from DM).		
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:44:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:44:37
Data point term sent to Coder	System	28 Aug 2020 15:43:54

**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition](#)

Audit	User	Time (GMT)
User entered 'PSORIASIS'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:43

**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2018'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:43

**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:43

**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:43

**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:43

**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:43:43

**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2018'	System	28 Aug 2020 15:43:43



**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2018'	System	28 Aug 2020 15:43:43

**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:43:43

**US3172360**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:43:43

US3172360

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:05:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:45:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:45:38
Data point term sent to Coder	System	28 Aug 2020 15:44:55
User entered 'ANXIETY'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:00

**US3172360**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2007'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:00

**US3172360**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:00

**US3172360**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:00

**US3172360**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	28 Aug 2020 15:44:00
	(b) (4)	



**US3172360**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:00

**US3172360**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2007'	System	28 Aug 2020 15:44:00

**US3172360**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2007'	System	28 Aug 2020 15:44:00

**US3172360**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:44:00

**US3172360**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:44:00

US3172360

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:05:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 15:44:56
User entered 'DEPRESSION'	Jessie Downs (b) (4)	28 Aug 2020 15:44:18
	(b) (4)	

**US3172360**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2007'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:18

**US3172360**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:18



**US3172360**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:18

**US3172360**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:18

**US3172360**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:18

**US3172360**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2007'	System	28 Aug 2020 15:44:18

**US3172360**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2007'	System	28 Aug 2020 15:44:18

**US3172360**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:44:18

**US3172360**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:44:18

US3172360

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:05:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 15:44:57
User entered 'INSOMNIA'	Jessie Downs (b) (4)	28 Aug 2020 15:44:38
	(b) (4)	



**US3172360**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2007'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:38

**US3172360**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:38

**US3172360**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:38

**US3172360**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:38

**US3172360**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:44:38

**US3172360**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2007'	System	28 Aug 2020 15:44:38

**US3172360**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2007'	System	28 Aug 2020 15:44:38

**US3172360**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:44:38



**US3172360**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:44:38

US3172360

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:05:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:46:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:46:41
Data point term sent to Coder	System	28 Aug 2020 15:45:58
User entered 'BIPOLAR DISORDER'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:06

**US3172360**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2007'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:06

**US3172360**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:06

**US3172360**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:06

**US3172360**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:06

**US3172360**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:06

**US3172360**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2007'	System	28 Aug 2020 15:45:06



**US3172360**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2007'	System	28 Aug 2020 15:45:06

**US3172360**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:45:06

**US3172360**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:45:06

US3172360

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:05:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Tobacco user - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:46:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:46:42
Data point term sent to Coder	System	28 Aug 2020 15:46:00
User entered 'CURRENT TOBACCO USER'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:25

**US3172360**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 1982'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:25

**US3172360**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:25

**US3172360**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:25

**US3172360**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:25



**US3172360**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:25

**US3172360**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 1982'	System	28 Aug 2020 15:45:25

**US3172360**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '1982'	System	28 Aug 2020 15:45:25

**US3172360**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:45:25

**US3172360**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:45:25

US3172360

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:05:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:46:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:46:42
Data point term sent to Coder	System	28 Aug 2020 15:46:01
User entered 'ALCOHOL CONSUMPTION'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:46

**US3172360**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 1982'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:46

**US3172360**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:46



US3172360

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:05:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:46

**US3172360**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	28 Aug 2020 15:45:46
	(b) (4)	

**US3172360**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:45:46

**US3172360**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 1982'	System	28 Aug 2020 15:45:46

**US3172360**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '1982'	System	28 Aug 2020 15:45:46

**US3172360**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:45:46

**US3172360**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:45:46

US3172360

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:05:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Social issues NEC, PT: Caffeine consumption, LLT: Caffeine consumption - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:47:44
Data point term sent to Coder	System	28 Aug 2020 15:47:01
User entered 'CAFFEINE CONSUMPTION'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:46:11



**US3172360**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 1982'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:46:11

**US3172360**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:46:11

**US3172360**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:46:11

**US3172360**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:46:11

**US3172360**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:46:11

**US3172360**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 1982'	System	28 Aug 2020 15:46:11

**US3172360**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '1982'	System	28 Aug 2020 15:46:11

**US3172360**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:46:11



**US3172360**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	28 Aug 2020 15:46:11

US3172360

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:05:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User coded data point as SOC: Cardiac disorders, HLGT: Pericardial disorders, HLT: Pericardial disorders NEC, PT: Pericardial fibrosis, LLT: Pericardial fibrosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 04:51:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 04:51:15
Data point term sent to Coder	System	28 Aug 2020 15:48:07
User entered 'PERICARDIAL SAC FIBROSIS'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:47:59

**US3172360**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2011'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:47:59

**US3172360**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:47:59

**US3172360**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:05:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:47:59

**US3172360**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'UN UNK 2011'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:47:59

**US3172360**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:05:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:47:59

**US3172360**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2011'	System	28 Aug 2020 15:47:59



**US3172360**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2011'	System	28 Aug 2020 15:47:59

**US3172360**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'Jan 2011'	System	28 Aug 2020 15:47:59

**US3172360**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '2011'	System	28 Aug 2020 15:47:59

US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '09:25'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '27 Aug 2020 09:25'	System	27 Aug 2020 16:37:49

US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '161.0' cm	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49
DataPoint set to visible.	System	27 Aug 2020 16:09:42



US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '081.3' kg	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49
DataPoint set to visible.	System	27 Aug 2020 16:09:42

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
Amendment Manager: User entered '31.36453'	System	17 Sep 2020 00:05:08
User entered '31.4'	System	27 Aug 2020 16:37:49
DataPoint set to visible.	System	27 Aug 2020 16:09:42

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'kg/m2'	System	27 Aug 2020 16:37:49
DataPoint set to visible.	System	27 Aug 2020 16:09:42

US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'bpm'	System	27 Aug 2020 16:37:49



US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'breaths/min'	System	27 Aug 2020 16:37:49

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'mmHg'	System	27 Aug 2020 16:37:49

US3172360

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:37:49

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'mmHg'	System	27 Aug 2020 16:37:49

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40

**US3172360**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40



US3172360

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Oct 2020 20:46:15
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	27 Aug 2020 16:38:15
	(b) (4)	

US3172360

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	02 Oct 2020 20:46:15
	(b) (4)	
User entered '27 Aug 2020'	Jessie Downs (b) (4)	27 Aug 2020 16:38:15
	(b) (4)	

US3172360

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:03:50

US3172360

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:52

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:03:50

**US3172360**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:05:52**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:03:50

US3172360

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:52

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:03:50

US3172360

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:03:50

**US3172360**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:05:52**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:03:50



US3172360

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:52

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:03:50

**US3172360**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:05:52**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:03:50

US3172360

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:04:31

US3172360

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:04:31

**US3172360**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Urine (URINE)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:04:31

**US3172360**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Negative (NEGATIVE)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:04:31

**US3172360**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:04:31

**US3172360**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	02 Oct 2020 20:47:02
	(b) (4)	
User entered '27 Aug 2020'	Jessie Downs (b) (4)	28 Aug 2020 14:04:31
	(b) (4)	



**US3172360**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	02 Oct 2020 20:47:02
	(b) (4)	
User entered '09:18'	Jessie Downs (b) (4)	28 Aug 2020 14:04:31
	(b) (4)	

**US3172360**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	02 Oct 2020 20:47:02
User entered '27 Aug 2020 09:18'	System	28 Aug 2020 14:04:31

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

[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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	27 Aug 2020 16:10:40
	(b) (4)	

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

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 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	27 Aug 2020 16:10:40
	(b) (4)	

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

[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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40



US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

[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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	27 Aug 2020 16:10:40
	(b) (4)	

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

**US3172360**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:05:52**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'DISABLED'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40



US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

**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 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'I'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'DORMITORY'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:10:40

US3172360

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:38:29



**US3172360**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:38:29

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:38:29

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'VISIT1'	System	27 Aug 2020 16:38:29

US3172360

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:49:56

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:05:52**

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '145121'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:49:56

US3172360

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:52

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:49:56

US3172360

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:52

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)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:09

US3172360

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:52

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)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:09



US3172360

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:52

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:09

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:05:52**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:09

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:05:52**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:09

US3172360

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:52

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 12:28:38
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	01 Dec 2020 16:29:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	01 Dec 2020 16:28:59
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 21:43:50
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:13:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:13:22

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08



US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '09:35'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '27 Aug 2020 09:35'	System	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Aug 2020 15:32:43
User entered '36.2' C reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Aug 2020 16:40:08
User entered '36.2' (non-conformant).	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08



US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '61'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'bpm'	System	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '15'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'breaths/min'	System	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '136'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'mmHg'	System	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '78'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'mmHg'	System	27 Aug 2020 16:40:08



US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 15:32:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 16:40:08
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '12:28' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '27 Aug 2020 12:28'	System	28 Aug 2020 15:32:43
User entered empty.	System	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '36.8' C reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08



US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '61' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'bpm'	System	28 Aug 2020 15:32:43
User entered empty.	System	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '14' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'breaths/min'	System	28 Aug 2020 15:32:43
User entered empty.	System	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '135' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'mmHg'	System	28 Aug 2020 15:32:43
User entered empty.	System	27 Aug 2020 16:40:08



US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '73' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'mmHg'	System	28 Aug 2020 15:32:43
User entered empty.	System	27 Aug 2020 16:40:08

US3172360

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:46:33
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:38:36

US3172360

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:46:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:38:36

US3172360

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:54:55
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:05:24

US3172360

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:54:55
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:05:24

US3172360

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:54:55
User entered 'Urine (URINE)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:05:24

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:54:55
User entered 'Negative (NEGATIVE)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:05:24



US3172360

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:54:55
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:05:24

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:54:55
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:05:24

US3172360

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:54:55
User entered '09:18'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 14:05:24

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	30 Sep 2020 14:54:55
User entered '27 Aug 2020 09:18'	System	28 Aug 2020 14:05:24

US3172360

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:36

US3172360

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:36

US3172360

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

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)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:36

US3172360

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 16:11:36



US3172360

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered '27 Aug 2020'	Jessie Downs (b) (4)	27 Aug 2020 16:11:36
	(b) (4)	

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '11:58'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:36

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '27 Aug 2020 11:58'	System	27 Aug 2020 16:11:36

US3172360

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:11:36

US3172360

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'ONCE'	System	27 Aug 2020 16:11:36

US3172360

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 16:11:36

US3172360

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:35

US3172360

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:35



**US3172360**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '11:32'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:40:35

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '27 Aug 2020 11:32'	System	27 Aug 2020 16:40:35

US3172360

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:41:22

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:41:22

US3172360

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:41:22

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:05:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '11:09'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:41:22

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '27 Aug 2020 11:09'	System	27 Aug 2020 16:41:22

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:41:22



US3172360

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:43:01
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:41:22

US3172360

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:43:01
User entered '11:09'	Jessie Downs (b) (4) (b) (4)	27 Aug 2020 16:41:22

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	17 Sep 2020 15:43:01
User entered '27 Aug 2020 11:09'	System	27 Aug 2020 16:41:22

US3172360

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 16:35:16

**US3172360**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '1'	System	04 Sep 2020 16:35:16

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:44:15', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8f75f960-cdf5-4914-9309-39753e911dc1'	System	27 Aug 2020 16:44:26
User entered 'Yes (Y)'	System	27 Aug 2020 16:44:26

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:44:02', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8f75f960-cdf5-4914-9309-39753e911dc1'	System	27 Aug 2020 16:44:26
User entered '98.3'	System	27 Aug 2020 16:44:26



US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:44:10', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8f75f960-cdf5-4914-9309-39753e911dc1'	System	27 Aug 2020 16:44:26
User entered 'No (N)'	System	27 Aug 2020 16:44:26

**US3172360**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:44:22', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8f75f960-cdf5-4914-9309-39753e911dc1'	System	27 Aug 2020 16:44:26
User entered '27 Aug 2020 12:44'	System	27 Aug 2020 16:44:26

**US3172360**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '27 Aug 2020 12:18'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '27 Aug 2020 14:48'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:08', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '89e8a60d-f8f6-4b1c-9fdd-b751a1d80f6b'	System	27 Aug 2020 21:18:26
User entered 'Yes (Y)'	System	27 Aug 2020 21:18:26

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:14', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '89e8a60d-f8f6-4b1c-9fdd-b751a1d80f6b'	System	27 Aug 2020 21:18:26
User entered '98.7'	System	27 Aug 2020 21:18:26

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:19', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '89e8a60d-f8f6-4b1c-9fdd-b751a1d80f6b'	System	27 Aug 2020 21:18:26
User entered 'No (N)'	System	27 Aug 2020 21:18:26



**US3172360**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:23', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '89e8a60d-f8f6-4b1c-9fdd-b751a1d80f6b'	System	27 Aug 2020 21:18:26
User entered '27 Aug 2020 17:18'	System	27 Aug 2020 21:18:26

**US3172360**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '27 Aug 2020 15:43'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 2'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:32:57', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8a03e296-1fbb-423a-b292-22d770ada76b'	System	28 Aug 2020 20:33:25
User entered 'Yes (Y)'	System	28 Aug 2020 20:33:25

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:11', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8a03e296-1fbb-423a-b292-22d770ada76b' User entered '97.8'	System	28 Aug 2020 20:33:25
	System	28 Aug 2020 20:33:25

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:17', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8a03e296-1fbb-423a-b292-22d770ada76b'	System	28 Aug 2020 20:33:25
User entered 'No (N)'	System	28 Aug 2020 20:33:25

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:22', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8a03e296-1fbb-423a-b292-22d770ada76b'	System	28 Aug 2020 20:33:25
User entered '28 Aug 2020 16:33'	System	28 Aug 2020 20:33:25



**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 3'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:30:24', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a1532bb2-eb6b-480b-a4ac-4ceb758b1141'	System	29 Aug 2020 21:30:41
User entered 'Yes (Y)'	System	29 Aug 2020 21:30:41

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:30:29', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a1532bb2-eb6b-480b-a4ac-4ceb758b1141'	System	29 Aug 2020 21:30:41
User entered '97.8'	System	29 Aug 2020 21:30:41

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:30:33', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a1532bb2-eb6b-480b-a4ac-4ceb758b1141'	System	29 Aug 2020 21:30:41
User entered 'No (N)'	System	29 Aug 2020 21:30:41

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:30:38', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a1532bb2-eb6b-480b-a4ac-4ceb758b1141'	System	29 Aug 2020 21:30:41
User entered '29 Aug 2020 17:30'	System	29 Aug 2020 21:30:41

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:11:36



**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 4'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:58:33', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd1708a4e-f980-4a2e-ace2-36e4acfc73e6'	System	30 Aug 2020 20:58:53
User entered 'Yes (Y)'	System	30 Aug 2020 20:58:53

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:58:42', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd1708a4e-f980-4a2e-ace2-36e4acfc73e6'	System	30 Aug 2020 20:58:53
User entered '98.4'	System	30 Aug 2020 20:58:53

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:58:45', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd1708a4e-f980-4a2e-ace2-36e4acfc73e6'	System	30 Aug 2020 20:58:53
User entered 'No (N)'	System	30 Aug 2020 20:58:53

**US3172360**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:58:47', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd1708a4e-f980-4a2e-ace2-36e4acfc73e6'	System	30 Aug 2020 20:58:53
User entered '30 Aug 2020 16:58'	System	30 Aug 2020 20:58:53

**US3172360**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 16:11:36



US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 5'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:23', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e6c6ffce-9c82-4031-9668-a3e9a552b20f'	System	31 Aug 2020 21:14:41
User entered 'Yes (Y)'	System	31 Aug 2020 21:14:41

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:29', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e6c6ffce-9c82-4031-9668-a3e9a552b20f' User entered '97.8'	System	31 Aug 2020 21:14:41
	System	31 Aug 2020 21:14:41

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:33', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e6c6ffce-9c82-4031-9668-a3e9a552b20f'	System	31 Aug 2020 21:14:41
User entered 'No (N)'	System	31 Aug 2020 21:14:41

**US3172360**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:36', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e6c6ffce-9c82-4031-9668-a3e9a552b20f'	System	31 Aug 2020 21:14:41
User entered '31 Aug 2020 17:14'	System	31 Aug 2020 21:14:41

**US3172360**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 6'	System	27 Aug 2020 16:11:36



US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:13', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '705dad0f-f8b5-40a6-9f38-0b02227f26ad'	System	01 Sep 2020 21:07:29
User entered 'Yes (Y)'	System	01 Sep 2020 21:07:29

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:18', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '705dad0f-f8b5-40a6-9f38-0b02227f26ad'	System	01 Sep 2020 21:07:29
User entered '98.2'	System	01 Sep 2020 21:07:29

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:23', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '705dad0f-f8b5-40a6-9f38-0b02227f26ad'	System	01 Sep 2020 21:07:29
User entered 'No (N)'	System	01 Sep 2020 21:07:29

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:26', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '705dad0f-f8b5-40a6-9f38-0b02227f26ad'	System	01 Sep 2020 21:07:29
User entered '01 Sep 2020 17:07'	System	01 Sep 2020 21:07:29

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 7'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:17', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ce628c65-73dc-4ace-ac73-6062d0e4ea42'	System	02 Sep 2020 19:45:36
User entered 'Yes (Y)'	System	02 Sep 2020 19:45:36



US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:22', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ce628c65-73dc-4ace-ac73-6062d0e4ea42'	System	02 Sep 2020 19:45:36
User entered '98.5'	System	02 Sep 2020 19:45:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:26', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ce628c65-73dc-4ace-ac73-6062d0e4ea42'	System	02 Sep 2020 19:45:36
User entered 'No (N)'	System	02 Sep 2020 19:45:36

US3172360

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:28', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ce628c65-73dc-4ace-ac73-6062d0e4ea42'	System	02 Sep 2020 19:45:36
User entered '02 Sep 2020 15:45'	System	02 Sep 2020 19:45:36

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:45:52', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '9aa4bc1b-2047-4865-9fe4-56ce1e45bab7'	System	27 Aug 2020 16:46:18
User entered 'None (1)'	System	27 Aug 2020 16:46:18

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:45:56', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '9aa4bc1b-2047-4865-9fe4-56ce1e45bab7'	System	27 Aug 2020 16:46:18
User entered 'No (N)'	System	27 Aug 2020 16:46:18



US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:02', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '9aa4bc1b-2047-4865-9fe4-56ce1e45bab7'	System	27 Aug 2020 16:46:18
User entered 'No (N)'	System	27 Aug 2020 16:46:18

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:07', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '9aa4bc1b-2047-4865-9fe4-56ce1e45bab7'	System	27 Aug 2020 16:46:18
User entered 'None (1)'	System	27 Aug 2020 16:46:18

**US3172360**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:14', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '9aa4bc1b-2047-4865-9fe4-56ce1e45bab7'	System	27 Aug 2020 16:46:18
User entered '27 Aug 2020 12:46'	System	27 Aug 2020 16:46:18

**US3172360**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '27 Aug 2020 12:18'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '27 Aug 2020 14:48'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:28', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '61920ca4-309a-42e7-adc8-e12f7bf81727'	System	27 Aug 2020 21:18:46
User entered 'None (1)'	System	27 Aug 2020 21:18:46

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:31', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '61920ca4-309a-42e7-adc8-e12f7bf81727'	System	27 Aug 2020 21:18:46
User entered 'No (N)'	System	27 Aug 2020 21:18:46



US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:34', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '61920ca4-309a-42e7-adc8-e12f7bf81727'	System	27 Aug 2020 21:18:46
User entered 'No (N)'	System	27 Aug 2020 21:18:46

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:36', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '61920ca4-309a-42e7-adc8-e12f7bf81727'	System	27 Aug 2020 21:18:46
User entered 'None (1)'	System	27 Aug 2020 21:18:46

**US3172360**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:39', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '61920ca4-309a-42e7-adc8-e12f7bf81727'	System	27 Aug 2020 21:18:46
User entered '27 Aug 2020 17:18'	System	27 Aug 2020 21:18:46

**US3172360**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '27 Aug 2020 15:43'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 2'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:32', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '49b951bf-4d3f-4b26-951c-4cf1822a5eea'	System	28 Aug 2020 20:33:54
User entered 'None (1)'	System	28 Aug 2020 20:33:54

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:35', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '49b951bf-4d3f-4b26-951c-4cf1822a5eea'	System	28 Aug 2020 20:33:54
User entered 'No (N)'	System	28 Aug 2020 20:33:54



US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:39', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '49b951bf-4d3f-4b26-951c-4cf1822a5eea'	System	28 Aug 2020 20:33:54
User entered 'No (N)'	System	28 Aug 2020 20:33:54

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:44', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '49b951bf-4d3f-4b26-951c-4cf1822a5eea'	System	28 Aug 2020 20:33:54
User entered 'None (1)'	System	28 Aug 2020 20:33:54

**US3172360**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:48', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '49b951bf-4d3f-4b26-951c-4cf1822a5eea'	System	28 Aug 2020 20:33:54
User entered '28 Aug 2020 16:33'	System	28 Aug 2020 20:33:54

**US3172360**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 3'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:30:43', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e7cb5c9b-0cd5-465b-b62c-e5dd3dacf57a'	System	29 Aug 2020 21:30:57
User entered 'None (1)'	System	29 Aug 2020 21:30:57

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:30:46', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e7cb5c9b-0cd5-465b-b62c-e5dd3dacf57a'	System	29 Aug 2020 21:30:57
User entered 'No (N)'	System	29 Aug 2020 21:30:57



US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:30:49', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e7cb5c9b-0cd5-465b-b62c-e5dd3dacf57a'	System	29 Aug 2020 21:30:57
User entered 'No (N)'	System	29 Aug 2020 21:30:57

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:30:51', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e7cb5c9b-0cd5-465b-b62c-e5dd3dacf57a'	System	29 Aug 2020 21:30:57
User entered 'None (1)'	System	29 Aug 2020 21:30:57

**US3172360**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:30:54', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e7cb5c9b-0cd5-465b-b62c-e5dd3dacf57a'	System	29 Aug 2020 21:30:57
User entered '29 Aug 2020 17:30'	System	29 Aug 2020 21:30:57

**US3172360**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 4'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:58:52', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '115cc26f-f79c-4ef5-bd04-0ee5eb0a19fa'	System	30 Aug 2020 20:59:04
User entered 'None (1)'	System	30 Aug 2020 20:59:04

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:58:54', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '115cc26f-f79c-4ef5-bd04-0ee5eb0a19fa'	System	30 Aug 2020 20:59:04
User entered 'No (N)'	System	30 Aug 2020 20:59:04



US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:58:57', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '115cc26f-f79c-4ef5-bd04-0ee5eb0a19fa'	System	30 Aug 2020 20:59:04
User entered 'No (N)'	System	30 Aug 2020 20:59:04

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:58:59', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '115cc26f-f79c-4ef5-bd04-0ee5eb0a19fa'	System	30 Aug 2020 20:59:04
User entered 'None (1)'	System	30 Aug 2020 20:59:04

**US3172360**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:59:01', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '115cc26f-f79c-4ef5-bd04-0ee5eb0a19fa'	System	30 Aug 2020 20:59:04
User entered '30 Aug 2020 16:59'	System	30 Aug 2020 20:59:04

**US3172360**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 5'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:40', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '4f7a5d25-3605-4e7f-9764-619533624075'	System	31 Aug 2020 21:14:53
User entered 'None (1)'	System	31 Aug 2020 21:14:53

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:43', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '4f7a5d25-3605-4e7f-9764-619533624075'	System	31 Aug 2020 21:14:53
User entered 'No (N)'	System	31 Aug 2020 21:14:53



US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:45', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '4f7a5d25-3605-4e7f-9764-619533624075'	System	31 Aug 2020 21:14:53
User entered 'No (N)'	System	31 Aug 2020 21:14:53

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:47', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '4f7a5d25-3605-4e7f-9764-619533624075'	System	31 Aug 2020 21:14:53
User entered 'None (1)'	System	31 Aug 2020 21:14:53

**US3172360**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:49', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '4f7a5d25-3605-4e7f-9764-619533624075'	System	31 Aug 2020 21:14:53
User entered '31 Aug 2020 17:14'	System	31 Aug 2020 21:14:53

**US3172360**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 6'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:31', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '76c3312e-1397-47b4-931d-0e4a0950410f'	System	01 Sep 2020 21:07:47
User entered 'None (1)'	System	01 Sep 2020 21:07:47

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:34', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '76c3312e-1397-47b4-931d-0e4a0950410f'	System	01 Sep 2020 21:07:47
User entered 'No (N)'	System	01 Sep 2020 21:07:47



US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:37', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '76c3312e-1397-47b4-931d-0e4a0950410f' User entered 'No (N)'	System	01 Sep 2020 21:07:47

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:40', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '76c3312e-1397-47b4-931d-0e4a0950410f'	System	01 Sep 2020 21:07:47
User entered 'None (1)'	System	01 Sep 2020 21:07:47

**US3172360**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:42', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '76c3312e-1397-47b4-931d-0e4a0950410f' User entered '01 Sep 2020 17:07'	System	01 Sep 2020 21:07:47
	System	01 Sep 2020 21:07:47

**US3172360**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 7'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:32', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'c5332e53-fbfa-4b4b-8d0e-9f093f6a033d'	System	02 Sep 2020 19:45:48
User entered 'None (1)'	System	02 Sep 2020 19:45:48

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:37', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'c5332e53-fbfa-4b4b-8d0e-9f093f6a033d'	System	02 Sep 2020 19:45:48
User entered 'No (N)'	System	02 Sep 2020 19:45:48



US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:39', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'c5332e53-fbfa-4b4b-8d0e-9f093f6a033d'	System	02 Sep 2020 19:45:48
User entered 'No (N)'	System	02 Sep 2020 19:45:48

US3172360

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:40', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'c5332e53-fbfa-4b4b-8d0e-9f093f6a033d'	System	02 Sep 2020 19:45:48
User entered 'None (1)'	System	02 Sep 2020 19:45:48

**US3172360**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:43', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'c5332e53-fbfa-4b4b-8d0e-9f093f6a033d'	System	02 Sep 2020 19:45:48
User entered '02 Sep 2020 15:45'	System	02 Sep 2020 19:45:48

**US3172360**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:19', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b40fd8f4-ef4d-45f9-8191-21a44dbea548'	System	27 Aug 2020 16:46:42
User entered 'None (0)'	System	27 Aug 2020 16:46:42

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:22', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b40fd8f4-ef4d-45f9-8191-21a44dbea548'	System	27 Aug 2020 16:46:42
User entered 'None (0)'	System	27 Aug 2020 16:46:42



US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:24', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b40fd8f4-ef4d-45f9-8191-21a44dbea548'	System	27 Aug 2020 16:46:42
User entered 'None (0)'	System	27 Aug 2020 16:46:42

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:27', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b40fd8f4-ef4d-45f9-8191-21a44dbea548'	System	27 Aug 2020 16:46:42
User entered 'None (0)'	System	27 Aug 2020 16:46:42

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:29', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b40fd8f4-ef4d-45f9-8191-21a44dbea548'	System	27 Aug 2020 16:46:42
User entered 'None (0)'	System	27 Aug 2020 16:46:42

**US3172360**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:32', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b40fd8f4-ef4d-45f9-8191-21a44dbea548'	System	27 Aug 2020 16:46:42
User entered 'None (0)'	System	27 Aug 2020 16:46:42

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:52

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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:35', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b40fd8f4-ef4d-45f9-8191-21a44dbea548'	System	27 Aug 2020 16:46:42
User entered 'No (N)'	System	27 Aug 2020 16:46:42

**US3172360**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T12:46:38', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b40fd8f4-ef4d-45f9-8191-21a44dbea548'	System	27 Aug 2020 16:46:42
User entered '27 Aug 2020 12:46'	System	27 Aug 2020 16:46:42

**US3172360**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '27 Aug 2020 12:18'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '27 Aug 2020 14:48'	System	27 Aug 2020 16:11:36



US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:44', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e0d12db4-7251-47f5-9eac-3f95203844b9'	System	27 Aug 2020 21:19:05
User entered 'None (0)'	System	27 Aug 2020 21:19:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:46', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e0d12db4-7251-47f5-9eac-3f95203844b9'	System	27 Aug 2020 21:19:05
User entered 'None (0)'	System	27 Aug 2020 21:19:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:48', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e0d12db4-7251-47f5-9eac-3f95203844b9'	System	27 Aug 2020 21:19:05
User entered 'None (0)'	System	27 Aug 2020 21:19:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:50', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e0d12db4-7251-47f5-9eac-3f95203844b9'	System	27 Aug 2020 21:19:05
User entered 'None (0)'	System	27 Aug 2020 21:19:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:52', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e0d12db4-7251-47f5-9eac-3f95203844b9'	System	27 Aug 2020 21:19:05
User entered 'None (0)'	System	27 Aug 2020 21:19:05

**US3172360**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:55', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e0d12db4-7251-47f5-9eac-3f95203844b9'	System	27 Aug 2020 21:19:05
User entered 'None (0)'	System	27 Aug 2020 21:19:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:52

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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:18:59', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e0d12db4-7251-47f5-9eac-3f95203844b9'	System	27 Aug 2020 21:19:05
User entered 'No (N)'	System	27 Aug 2020 21:19:05



**US3172360**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-27T17:19:02', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'e0d12db4-7251-47f5-9eac-3f95203844b9'	System	27 Aug 2020 21:19:05
User entered '27 Aug 2020 17:19'	System	27 Aug 2020 21:19:05

**US3172360**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '27 Aug 2020 15:43'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 2'	System	27 Aug 2020 16:11:36

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:53', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '77d07712-bc9c-4320-b2aa-ad565104b2a7'	System	28 Aug 2020 20:34:16
User entered 'None (0)'	System	28 Aug 2020 20:34:16

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:56', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '77d07712-bc9c-4320-b2aa-ad565104b2a7'	System	28 Aug 2020 20:34:16
User entered 'None (0)'	System	28 Aug 2020 20:34:16

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:33:59', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '77d07712-bc9c-4320-b2aa-ad565104b2a7'	System	28 Aug 2020 20:34:16
User entered 'None (0)'	System	28 Aug 2020 20:34:16

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:34:01', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '77d07712-bc9c-4320-b2aa-ad565104b2a7'	System	28 Aug 2020 20:34:16
User entered 'None (0)'	System	28 Aug 2020 20:34:16



**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:34:03', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '77d07712-bc9c-4320-b2aa-ad565104b2a7'	System	28 Aug 2020 20:34:16
User entered 'None (0)'	System	28 Aug 2020 20:34:16

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:34:07', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '77d07712-bc9c-4320-b2aa-ad565104b2a7'	System	28 Aug 2020 20:34:16
User entered 'None (0)'	System	28 Aug 2020 20:34:16

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:52

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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:34:10', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '77d07712-bc9c-4320-b2aa-ad565104b2a7'	System	28 Aug 2020 20:34:16
User entered 'No (N)'	System	28 Aug 2020 20:34:16

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-28T16:34:12', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '77d07712-bc9c-4320-b2aa-ad565104b2a7'	System	28 Aug 2020 20:34:16
User entered '28 Aug 2020 16:34'	System	28 Aug 2020 20:34:16

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 3'	System	27 Aug 2020 16:11:36

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:31:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '172cd847-27e0-43de-a93d-519901b39ee1' User entered 'None (0)'	System	29 Aug 2020 21:31:27
	System	29 Aug 2020 21:31:27



**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:31:02', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '172cd847-27e0-43de-a93d-519901b39ee1'	System	29 Aug 2020 21:31:27
User entered 'None (0)'	System	29 Aug 2020 21:31:27

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:31:04', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '172cd847-27e0-43de-a93d-519901b39ee1'	System	29 Aug 2020 21:31:27
User entered 'None (0)'	System	29 Aug 2020 21:31:27

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:31:06', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '172cd847-27e0-43de-a93d-519901b39ee1'	System	29 Aug 2020 21:31:27
User entered 'None (0)'	System	29 Aug 2020 21:31:27

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:31:10', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '172cd847-27e0-43de-a93d-519901b39ee1'	System	29 Aug 2020 21:31:27
User entered 'None (0)'	System	29 Aug 2020 21:31:27

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:31:12', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '172cd847-27e0-43de-a93d-519901b39ee1'	System	29 Aug 2020 21:31:27
User entered 'None (0)'	System	29 Aug 2020 21:31:27

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:52

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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:31:16', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '172cd847-27e0-43de-a93d-519901b39ee1'	System	29 Aug 2020 21:31:27
User entered 'No (N)'	System	29 Aug 2020 21:31:27

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-29T17:31:25', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '172cd847-27e0-43de-a93d-519901b39ee1'	System	29 Aug 2020 21:31:27
User entered '29 Aug 2020 17:31'	System	29 Aug 2020 21:31:27

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:11:36



**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 4'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:59:06', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd77fbdf6-f4fc-4ca6-b0dc-dbe763d15037'	System	30 Aug 2020 20:59:28
User entered 'None (0)'	System	30 Aug 2020 20:59:28

**US3172360**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:59:08', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd77fbdf6-f4fc-4ca6-b0dc-dbe763d15037'	System	30 Aug 2020 20:59:28
User entered 'None (0)'	System	30 Aug 2020 20:59:28

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:59:10', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd77fbdf6-f4fc-4ca6-b0dc-dbe763d15037'	System	30 Aug 2020 20:59:28
User entered 'None (0)'	System	30 Aug 2020 20:59:28

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:59:12', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd77fbdf6-f4fc-4ca6-b0dc-dbe763d15037'	System	30 Aug 2020 20:59:28
User entered 'None (0)'	System	30 Aug 2020 20:59:28

**US3172360**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:59:14', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd77fbdf6-f4fc-4ca6-b0dc-dbe763d15037'	System	30 Aug 2020 20:59:28
User entered 'None (0)'	System	30 Aug 2020 20:59:28

**US3172360**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:59:16', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd77fbdf6-f4fc-4ca6-b0dc-dbe763d15037'	System	30 Aug 2020 20:59:28
User entered 'None (0)'	System	30 Aug 2020 20:59:28



US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:52

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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:59:20', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd77fbdf6-f4fc-4ca6-b0dc-dbe763d15037'	System	30 Aug 2020 20:59:28
User entered 'No (N)'	System	30 Aug 2020 20:59:28

**US3172360**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-30T16:59:22', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd77fbdf6-f4fc-4ca6-b0dc-dbe763d15037'	System	30 Aug 2020 20:59:28
User entered '30 Aug 2020 16:59'	System	30 Aug 2020 20:59:28

**US3172360**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 5'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:54', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1ab79053-1252-4d17-b1cd-c9d7bf886851'	System	31 Aug 2020 21:15:15
User entered 'None (0)'	System	31 Aug 2020 21:15:15

**US3172360**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:56', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1ab79053-1252-4d17-b1cd-c9d7bf886851'	System	31 Aug 2020 21:15:15
User entered 'None (0)'	System	31 Aug 2020 21:15:15

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:14:58', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1ab79053-1252-4d17-b1cd-c9d7bf886851'	System	31 Aug 2020 21:15:15
User entered 'None (0)'	System	31 Aug 2020 21:15:15



US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:15:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1ab79053-1252-4d17-b1cd-c9d7bf886851'	System	31 Aug 2020 21:15:15
User entered 'None (0)'	System	31 Aug 2020 21:15:15

**US3172360**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:15:02', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1ab79053-1252-4d17-b1cd-c9d7bf886851'	System	31 Aug 2020 21:15:15
User entered 'None (0)'	System	31 Aug 2020 21:15:15

**US3172360**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:15:04', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1ab79053-1252-4d17-b1cd-c9d7bf886851'	System	31 Aug 2020 21:15:15
User entered 'None (0)'	System	31 Aug 2020 21:15:15

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:52

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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:15:06', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1ab79053-1252-4d17-b1cd-c9d7bf886851'	System	31 Aug 2020 21:15:15
User entered 'No (N)'	System	31 Aug 2020 21:15:15

**US3172360**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-08-31T17:15:09', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1ab79053-1252-4d17-b1cd-c9d7bf886851'	System	31 Aug 2020 21:15:15
User entered '31 Aug 2020 17:15'	System	31 Aug 2020 21:15:15

**US3172360**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 6'	System	27 Aug 2020 16:11:36



US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:47', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1c48e5c8-e0a4-4683-894f-0db37c370090' User entered 'None (0)'	System	01 Sep 2020 21:08:10
	System	01 Sep 2020 21:08:10

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:49', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1c48e5c8-e0a4-4683-894f-0db37c370090'	System	01 Sep 2020 21:08:10
User entered 'None (0)'	System	01 Sep 2020 21:08:10

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:51', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1c48e5c8-e0a4-4683-894f-0db37c370090'	System	01 Sep 2020 21:08:10
User entered 'None (0)'	System	01 Sep 2020 21:08:10

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:53', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1c48e5c8-e0a4-4683-894f-0db37c370090'	System	01 Sep 2020 21:08:10
User entered 'None (0)'	System	01 Sep 2020 21:08:10

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:56', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1c48e5c8-e0a4-4683-894f-0db37c370090'	System	01 Sep 2020 21:08:10
User entered 'None (0)'	System	01 Sep 2020 21:08:10

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:07:58', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1c48e5c8-e0a4-4683-894f-0db37c370090'	System	01 Sep 2020 21:08:10
User entered 'None (0)'	System	01 Sep 2020 21:08:10

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:52

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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:08:01', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1c48e5c8-e0a4-4683-894f-0db37c370090'	System	01 Sep 2020 21:08:10
User entered 'No (N)'	System	01 Sep 2020 21:08:10

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-01T17:08:03', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '1c48e5c8-e0a4-4683-894f-0db37c370090'	System	01 Sep 2020 21:08:10
User entered '01 Sep 2020 17:08'	System	01 Sep 2020 21:08:10



**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 7'	System	27 Aug 2020 16:11:36

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:47', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ba0ef6be-cb02-4578-a778-50e2b4eee81a'	System	02 Sep 2020 19:46:05
User entered 'None (0)'	System	02 Sep 2020 19:46:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:49', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ba0ef6be-cb02-4578-a778-50e2b4eee81a'	System	02 Sep 2020 19:46:05
User entered 'None (0)'	System	02 Sep 2020 19:46:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:50', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ba0ef6be-cb02-4578-a778-50e2b4eee81a'	System	02 Sep 2020 19:46:05
User entered 'None (0)'	System	02 Sep 2020 19:46:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:52', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ba0ef6be-cb02-4578-a778-50e2b4eee81a'	System	02 Sep 2020 19:46:05
User entered 'None (0)'	System	02 Sep 2020 19:46:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:55', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ba0ef6be-cb02-4578-a778-50e2b4eee81a'	System	02 Sep 2020 19:46:05
User entered 'None (0)'	System	02 Sep 2020 19:46:05



**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:57', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ba0ef6be-cb02-4578-a778-50e2b4eee81a'	System	02 Sep 2020 19:46:05
User entered 'None (0)'	System	02 Sep 2020 19:46:05

US3172360

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:52

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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:45:59', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ba0ef6be-cb02-4578-a778-50e2b4eee81a'	System	02 Sep 2020 19:46:05
User entered 'No (N)'	System	02 Sep 2020 19:46:05

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-09-02T15:46:02', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ba0ef6be-cb02-4578-a778-50e2b4eee81a'	System	02 Sep 2020 19:46:05
User entered '02 Sep 2020 15:46'	System	02 Sep 2020 19:46:05

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 16:11:36

**US3172360**

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

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

**Generated On: 11 Aug 2021 22:05:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 16:11:36

**US3172360**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 16:35:39

**US3172360**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered '04 Sep 2020'	Jessie Downs (b) (4)	04 Sep 2020 16:35:39
	(b) (4)	

**US3172360**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 16:35:39



US3172360

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 16:35:39

US3172360

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 16:35:42

**US3172360**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'I'	System	04 Sep 2020 16:35:42

**US3172360**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 19:42:51

US3172360

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 16:01:21
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 19:44:29
answered with 'Sub I was able to get in contact with subject on September 14, 2020' (Site from System).		
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 19:42:51
User entered '14 Sep 2020'	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 19:42:51

**US3172360**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 19:42:51

US3172360

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 19:42:51

US3172360

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 19:44:33



**US3172360**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '1'	System	14 Sep 2020 19:44:33

**US3172360**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 20:08:24

US3172360

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '17 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 20:08:24

**US3172360**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 20:08:24

US3172360

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 20:08:24

US3172360

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 20:08:28

**US3172360**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '1'	System	17 Sep 2020 20:08:28

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:44



**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:44

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:44

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'VISIT2'	System	22 Sep 2020 18:52:44

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '07:57'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '22 Sep 2020 07:57'	System	22 Sep 2020 18:53:23



US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '36.7' C	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '71'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'bpm'	System	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '16'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'breaths/min'	System	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '136'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23



**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'mmHg'	System	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '82'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'mmHg'	System	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:53:23



US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23



US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:53:23

US3172360

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:42

US3172360

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:53:42

US3172360

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:34

US3172360

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:34

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Urine (URINE)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:34



**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Negative (NEGATIVE)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:34

US3172360

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:34

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:34

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:52:34

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:52:34

US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:01

US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:01

US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

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)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:01



US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:56:01

US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:01

US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:01

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:56:01

US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:01

US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:56:01

US3172360

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:56:01

US3172360

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:40



US3172360

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 22SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:17:31
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 22SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'Confirmed, Sample shipped on 29SEP20.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 14:13:04
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 22SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:52:04
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:40

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '09:51'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:40

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '22 Sep 2020 09:51'	System	22 Sep 2020 18:56:40

US3172360

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:54

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:54

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:54

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:05:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '09:36'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:54

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '22 Sep 2020 09:36'	System	22 Sep 2020 18:56:54



**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:54

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:54

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:05:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:54

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered empty.	System	22 Sep 2020 18:56:54

US3172360

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 18:56:57

**US3172360**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'I'	System	22 Sep 2020 18:56:57

**US3172360**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 15:04:46

**US3172360**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered '29 Sep 2020'	Jessie Downs (b) (4)	30 Sep 2020 15:04:46
	(b) (4)	



**US3172360**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 15:04:46

US3172360

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 15:04:46

US3172360

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 20:38:49
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 18:41:47
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 15:04:52

**US3172360**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '1'	System	08 Oct 2020 20:38:49
User entered empty.	System	07 Oct 2020 18:41:47
User entered '1'	System	30 Sep 2020 15:04:52

**US3172360**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 20:39:02

**US3172360**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered '06 Oct 2020'	Jessie Downs (b) (4)	08 Oct 2020 20:39:02
	(b) (4)	

**US3172360**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 20:39:02

US3172360

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 20:39:02



US3172360

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:19:25
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 20:39:07

**US3172360**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '1'	System	22 Oct 2020 18:19:25
User entered empty.	System	08 Oct 2020 20:39:07

**US3172360**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 17:46:44
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:19:39

US3172360

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '14 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 17:46:44
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:19:39

US3172360

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 17:46:44
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:19:39

US3172360

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:19:39

**US3172360**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:19:31

**US3172360**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'I'	System	22 Oct 2020 18:19:31



**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:19:49

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '22 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:19:49

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:19:49

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'VISIT3'	System	22 Oct 2020 18:19:49

US3172360

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '22 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '11:28'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '22 Oct 2020 11:28'	System	22 Oct 2020 18:20:37



US3172360

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '36.5' C	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '65'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'bpm'	System	22 Oct 2020 18:20:37

US3172360

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '13'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'breaths/min'	System	22 Oct 2020 18:20:37

US3172360

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '136'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37



**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'mmHg'	System	22 Oct 2020 18:20:37

US3172360

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '79'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'mmHg'	System	22 Oct 2020 18:20:37

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58

US3172360

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:44

US3172360

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:44

US3172360

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:57



US3172360

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '22 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:57

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '11:58'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:20:57

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '22 Oct 2020 11:58'	System	22 Oct 2020 18:20:57

US3172360

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:41:03
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 18:21:17

**US3172360**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered '1'	System	18 Nov 2020 14:41:03
User entered empty.	System	22 Oct 2020 18:21:17

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 64'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-10-27T00:29:28', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '42fc45ba-5ef5-4d93-9c23-f23f71ac2c9d'	System	27 Oct 2020 04:29:43
User entered 'No (N)'	System	27 Oct 2020 04:29:43

US3172360

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:52

Have you been exposed to someone with 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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-10-27T00:29:33', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '42fc45ba-5ef5-4d93-9c23-f23f71ac2c9d'	System	27 Oct 2020 04:29:43
User entered 'No (N)'	System	27 Oct 2020 04:29:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-10-27T00:29:36', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '42fc45ba-5ef5-4d93-9c23-f23f71ac2c9d' User entered '27 Oct 2020 00:29:36'	System	27 Oct 2020 04:29:43
	System	27 Oct 2020 04:29:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 71'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-11-03T01:39:25', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'f81345b6-8124-4178-be2c-2a21086f0303'	System	03 Nov 2020 06:39:39
User entered 'No (N)'	System	03 Nov 2020 06:39:39

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Have you been exposed to someone with 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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-11-03T01:39:28', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'f81345b6-8124-4178-be2c-2a21086f0303'	System	03 Nov 2020 06:39:39
User entered 'No (N)'	System	03 Nov 2020 06:39:39

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-11-03T01:39:35', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'f81345b6-8124-4178-be2c-2a21086f0303'	System	03 Nov 2020 06:39:39
User entered '03 Nov 2020 01:39:35'	System	03 Nov 2020 06:39:39

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 16:11:36



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered 'Day 78'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-11-10T01:02:54', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '5c528e0d-10d9-4084-bc57-beb2c4942601'	System	10 Nov 2020 06:03:08
User entered 'No (N)'	System	10 Nov 2020 06:03:08

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Have you been exposed to someone with 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)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-11-10T01:02:59', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '5c528e0d-10d9-4084-bc57-beb2c4942601'	System	10 Nov 2020 06:03:08
User entered 'No (N)'	System	10 Nov 2020 06:03:08

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-11-10T01:03:03', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '5c528e0d-10d9-4084-bc57-beb2c4942601' User entered '10 Nov 2020 01:03:03'	System	10 Nov 2020 06:03:08
	System	10 Nov 2020 06:03:08

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:57:57
Data entry locked.	System	27 Aug 2020 16:11:36
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 16:11:36

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:53:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2020-11-21T00:33:42', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'bcc7b825-d3f0-41c7-b90e-5e3448011768'	System	21 Nov 2020 05:37:05
User entered 'No (N)'	System	21 Nov 2020 05:37:05

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2020-11-21T00:33:46', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'bcc7b825-d3f0-41c7-b90e-5e3448011768'	System	21 Nov 2020 05:37:05
User entered 'No (N)'	System	21 Nov 2020 05:37:05

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-11-21T00:33:49', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'bcc7b825-d3f0-41c7-b90e-5e3448011768' User entered '21 Nov 2020 00:33:49'	System	21 Nov 2020 05:37:05
	System	21 Nov 2020 05:37:05

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2020-11-28T02:05:25', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '24888ea8-509b-4f3f-8128-d8f627cbffda'	System	28 Nov 2020 07:05:40
User entered 'No (N)'	System	28 Nov 2020 07:05:40

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2020-11-28T02:05:28', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '24888ea8-509b-4f3f-8128-d8f627cbffda'	System	28 Nov 2020 07:05:40
User entered 'No (N)'	System	28 Nov 2020 07:05:40



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-11-28T02:05:30', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '24888ea8-509b-4f3f-8128-d8f627cbffda'	System	28 Nov 2020 07:05:40
User entered '28 Nov 2020 02:05:30'	System	28 Nov 2020 07:05:40

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2020-12-05T00:02:33', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'de075b72-2d48-4cd8-a468-811fe8b72382'	System	05 Dec 2020 05:02:48
User entered 'No (N)'	System	05 Dec 2020 05:02:48

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2020-12-05T00:02:35', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'de075b72-2d48-4cd8-a468-811fe8b72382'	System	05 Dec 2020 05:02:48
User entered 'No (N)'	System	05 Dec 2020 05:02:48

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-12-05T00:02:39', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'de075b72-2d48-4cd8-a468-811fe8b72382'	System	05 Dec 2020 05:02:48
User entered '05 Dec 2020 00:02:39'	System	05 Dec 2020 05:02:48

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2020-12-15T00:30:45', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8556aaa1-08ba-428b-8d7c-29e572061c7a'	System	15 Dec 2020 05:30:55
User entered 'No (N)'	System	15 Dec 2020 05:30:55

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2020-12-15T00:30:47', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8556aaa1-08ba-428b-8d7c-29e572061c7a'	System	15 Dec 2020 05:30:55
User entered 'No (N)'	System	15 Dec 2020 05:30:55

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-12-15T00:30:50', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '8556aaa1-08ba-428b-8d7c-29e572061c7a'	System	15 Dec 2020 05:30:55
User entered '15 Dec 2020 00:30:50'	System	15 Dec 2020 05:30:55

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:53:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2020-12-19T00:02:31', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'f65b8b04-9791-4ae4-ae5a-24344399b641'	System	19 Dec 2020 05:03:18
User entered 'No (N)'	System	19 Dec 2020 05:03:18

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2020-12-19T00:02:33', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'f65b8b04-9791-4ae4-ae5a-24344399b641'	System	19 Dec 2020 05:03:18
User entered 'No (N)'	System	19 Dec 2020 05:03:18

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-12-19T00:02:37', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'f65b8b04-9791-4ae4-ae5a-24344399b641'	System	19 Dec 2020 05:03:18
User entered '19 Dec 2020 00:02:37'	System	19 Dec 2020 05:03:18

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2020-12-26T02:12:16', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '0019ba94-9f86-43aa-b9ca-eea197a6c65e'	System	26 Dec 2020 07:12:25
User entered 'No (N)'	System	26 Dec 2020 07:12:25

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2020-12-26T02:12:19', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '0019ba94-9f86-43aa-b9ca-eea197a6c65e'	System	26 Dec 2020 07:12:25
User entered 'No (N)'	System	26 Dec 2020 07:12:25



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2020-12-26T02:12:21', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '0019ba94-9f86-43aa-b9ca-eea197a6c65e' User entered '26 Dec 2020 02:12:21'	System	26 Dec 2020 07:12:25
	System	26 Dec 2020 07:12:25

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-01-02T00:01:56', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a6a255bd-778b-44e2-b5d8-51255ab9f5bc'	System	02 Jan 2021 05:02:45
User entered 'No (N)'	System	02 Jan 2021 05:02:45

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-01-02T00:01:58', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a6a255bd-778b-44e2-b5d8-51255ab9f5bc'	System	02 Jan 2021 05:02:45
User entered 'No (N)'	System	02 Jan 2021 05:02:45

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-01-02T00:02:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a6a255bd-778b-44e2-b5d8-51255ab9f5bc'	System	02 Jan 2021 05:02:45
User entered '02 Jan 2021 00:02:00'	System	02 Jan 2021 05:02:45

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-01-09T00:03:46', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b5a4de82-536a-4e76-a173-13fa5b917d89'	System	09 Jan 2021 05:03:58
User entered 'No (N)'	System	09 Jan 2021 05:03:58

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-01-09T00:03:48', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b5a4de82-536a-4e76-a173-13fa5b917d89'	System	09 Jan 2021 05:03:58
User entered 'No (N)'	System	09 Jan 2021 05:03:58

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-01-09T00:03:51', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'b5a4de82-536a-4e76-a173-13fa5b917d89'	System	09 Jan 2021 05:03:58
User entered '09 Jan 2021 00:03:51'	System	09 Jan 2021 05:03:58

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:53:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-01-16T00:38:43', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'fec12b3f-6655-4a0e-a6ba-c445cc7b71e4'	System	16 Jan 2021 05:41:31
User entered 'No (N)'	System	16 Jan 2021 05:41:31

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-01-16T00:38:46', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'fec12b3f-6655-4a0e-a6ba-c445cc7b71e4'	System	16 Jan 2021 05:41:31
User entered 'No (N)'	System	16 Jan 2021 05:41:31

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-01-16T00:38:49', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'fec12b3f-6655-4a0e-a6ba-c445cc7b71e4' User entered '16 Jan 2021 00:38:49'	System	16 Jan 2021 05:41:31

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-01-23T00:01:41', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '06bb324a-bfde-4fbf-bb09-76390a4def48'	System	23 Jan 2021 05:02:22
User entered 'No (N)'	System	23 Jan 2021 05:02:22

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-01-23T00:01:44', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '06bb324a-bfde-4fbf-bb09-76390a4def48'	System	23 Jan 2021 05:02:22
User entered 'No (N)'	System	23 Jan 2021 05:02:22



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-01-23T00:01:49', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '06bb324a-bfde-4fbf-bb09-76390a4def48'	System	23 Jan 2021 05:02:22
User entered '23 Jan 2021 00:01:49'	System	23 Jan 2021 05:02:22

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-01-30T01:34:10', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '4eaaf8a4-d6a1-4fb7-833b-2e32b14d522d'	System	30 Jan 2021 06:34:18
User entered 'No (N)'	System	30 Jan 2021 06:34:18

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-01-30T01:34:07', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '4eaaf8a4-d6a1-4fb7-833b-2e32b14d522d'	System	30 Jan 2021 06:34:18
User entered 'No (N)'	System	30 Jan 2021 06:34:18

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-01-30T01:34:15', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '4eaaf8a4-d6a1-4fb7-833b-2e32b14d522d' User entered '30 Jan 2021 01:34:15'	System	30 Jan 2021 06:34:18

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-02-07T20:31:41', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '197090df-2b9e-4f4c-8fb6-06e2d338d164'	System	08 Feb 2021 01:31:50
User entered 'No (N)'	System	08 Feb 2021 01:31:50

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-02-07T20:31:43', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '197090df-2b9e-4f4c-8fb6-06e2d338d164'	System	08 Feb 2021 01:31:50
User entered 'No (N)'	System	08 Feb 2021 01:31:50

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-02-07T20:31:46', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '197090df-2b9e-4f4c-8fb6-06e2d338d164'	System	08 Feb 2021 01:31:50
User entered '07 Feb 2021 20:31:46'	System	08 Feb 2021 01:31:50

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:53:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-02-13T00:04:20', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '6f115518-f7cd-4e12-ba70-cd17268cc573'	System	13 Feb 2021 05:05:14
User entered 'No (N)'	System	13 Feb 2021 05:05:14

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-02-13T00:04:22', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '6f115518-f7cd-4e12-ba70-cd17268cc573'	System	13 Feb 2021 05:05:14
User entered 'No (N)'	System	13 Feb 2021 05:05:14

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-02-13T00:04:25', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '6f115518-f7cd-4e12-ba70-cd17268cc573'	System	13 Feb 2021 05:05:14
User entered '13 Feb 2021 00:04:25'	System	13 Feb 2021 05:05:14

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-02-20T00:13:42', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'f53081e6-75cb-403e-8bb9-9a061e22ba1b'	System	20 Feb 2021 05:13:52
User entered 'No (N)'	System	20 Feb 2021 05:13:52

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-02-20T00:13:44', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'f53081e6-75cb-403e-8bb9-9a061e22ba1b'	System	20 Feb 2021 05:13:52
User entered 'No (N)'	System	20 Feb 2021 05:13:52



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-02-20T00:13:46', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'f53081e6-75cb-403e-8bb9-9a061e22ba1b' User entered '20 Feb 2021 00:13:46'	System	20 Feb 2021 05:13:52

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-02-27T00:01:23-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '293cb360-98d3-4fe2-a431-1f037cb75415'	System	27 Feb 2021 05:03:29
User entered 'No (N)'	System	27 Feb 2021 05:03:29

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-02-27T00:01:25-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '293cb360-98d3-4fe2-a431-1f037cb75415'	System	27 Feb 2021 05:03:29
User entered 'No (N)'	System	27 Feb 2021 05:03:29

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-02-27T00:01:29-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '293cb360-98d3-4fe2-a431-1f037cb75415'	System	27 Feb 2021 05:03:29
User entered '27 Feb 2021 00:01:29'	System	27 Feb 2021 05:03:29

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-03-06T00:01:23-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '282afb13-8180-4195-9d48-1fead9cee648'	System	06 Mar 2021 05:02:56
User entered 'No (N)'	System	06 Mar 2021 05:02:56

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-03-06T00:01:25-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '282afb13-8180-4195-9d48-1fead9cee648'	System	06 Mar 2021 05:02:56
User entered 'No (N)'	System	06 Mar 2021 05:02:56

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-03-06T00:01:28-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '282afb13-8180-4195-9d48-1fead9cee648'	System	06 Mar 2021 05:02:56
User entered '06 Mar 2021 00:01:28'	System	06 Mar 2021 05:02:56

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:53:43



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (65c0baceb67112c1)', Time: '2021-03-13T20:25:31-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'aa838aad-a4bd-427a-a356-50bf55717c91'	System	14 Mar 2021 01:25:41
User entered 'No (N)'	System	14 Mar 2021 01:25:41

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (65c0baceb67112c1)', Time: '2021-03-13T20:25:34-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'aa838aad-a4bd-427a-a356-50bf55717c91'	System	14 Mar 2021 01:25:41
User entered 'No (N)'	System	14 Mar 2021 01:25:41

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-03-13T20:25:38-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'aa838aad-a4bd-427a-a356-50bf55717c91'	System	14 Mar 2021 01:25:41
User entered '13 Mar 2021 20:25:38'	System	14 Mar 2021 01:25:41

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (af19d8852fb01bdb)', Time: '2021-03-23T10:12:45-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '55a9d2a6-7580-489e-9879-4af69dda7424'	System	23 Mar 2021 14:12:53
User entered 'No (N)'	System	23 Mar 2021 14:12:53

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (af19d8852fb01bdb)', Time: '2021-03-23T10:12:47-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '55a9d2a6-7580-489e-9879-4af69dda7424'	System	23 Mar 2021 14:12:53
User entered 'No (N)'	System	23 Mar 2021 14:12:53



**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (af19d8852fb01bdb)', Time: '2021-03-23T10:12:50-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '55a9d2a6-7580-489e-9879-4af69dda7424'	System	23 Mar 2021 14:12:53
User entered '23 Mar 2021 10:12:50'	System	23 Mar 2021 14:12:53

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:53:43

**US3172360**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (af19d8852fb01bdb)', Time: '2021-03-28T02:02:46-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'cd0b4e0c-d326-43d0-8af0-01c97063af38'	System	28 Mar 2021 06:02:57
User entered 'No (N)'	System	28 Mar 2021 06:02:57

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (af19d8852fb01bdb)', Time: '2021-03-28T02:02:50-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'cd0b4e0c-d326-43d0-8af0-01c97063af38'	System	28 Mar 2021 06:02:57
User entered 'No (N)'	System	28 Mar 2021 06:02:57

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (af19d8852fb01bdb)', Time: '2021-03-28T02:02:53-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'cd0b4e0c-d326-43d0-8af0-01c97063af38'	System	28 Mar 2021 06:02:57
User entered '28 Mar 2021 02:02:53'	System	28 Mar 2021 06:02:57

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (af19d8852fb01bdb)', Time: '2021-04-03T01:57:01-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '34a3ccf2-cd08-41de-9b4c-b8ea1d9cfcb0'	System	03 Apr 2021 06:04:09
User entered 'No (N)'	System	03 Apr 2021 06:04:09

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (af19d8852fb01bdb)', Time: '2021-04-03T01:57:03-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '34a3ccf2-cd08-41de-9b4c-b8ea1d9cfcb0'	System	03 Apr 2021 06:04:09
User entered 'No (N)'	System	03 Apr 2021 06:04:09

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (af19d8852fb01bdb)', Time: '2021-04-03T01:57:14-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '34a3ccf2-cd08-41de-9b4c-b8ea1d9cfcb0'	System	03 Apr 2021 06:04:09
User entered '03 Apr 2021 01:57:14'	System	03 Apr 2021 06:04:09

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (af19d8852fb01bdb)', Time: '2021-04-10T01:03:48-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '3a4879b9-d20e-40e0-b5dc-29a280a08c37'	System	10 Apr 2021 05:04:03
User entered 'No (N)'	System	10 Apr 2021 05:04:03

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (af19d8852fb01bdb)', Time: '2021-04-10T01:03:50-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '3a4879b9-d20e-40e0-b5dc-29a280a08c37'	System	10 Apr 2021 05:04:03
User entered 'No (N)'	System	10 Apr 2021 05:04:03

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (af19d8852fb01bdb)', Time: '2021-04-10T01:03:57-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '3a4879b9-d20e-40e0-b5dc-29a280a08c37'	System	10 Apr 2021 05:04:03
User entered '10 Apr 2021 01:03:57'	System	10 Apr 2021 05:04:03

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (cf934bbf84e46c9d)', Time: '2021-04-17T00:46:34-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a92ff775-2cd1-445c-ac6a-b512a215d993'	System	17 Apr 2021 04:46:44
User entered 'No (N)'	System	17 Apr 2021 04:46:44

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Have you been exposed to someone with 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 (cf934bbf84e46c9d)', Time: '2021-04-17T00:46:36-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a92ff775-2cd1-445c-ac6a-b512a215d993'	System	17 Apr 2021 04:46:44
User entered 'No (N)'	System	17 Apr 2021 04:46:44



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cf934bbf84e46c9d)', Time: '2021-04-17T00:46:39-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'a92ff775-2cd1-445c-ac6a-b512a215d993'	System	17 Apr 2021 04:46:44
User entered '17 Apr 2021 00:46:39'	System	17 Apr 2021 04:46:44

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (cf934bbf84e46c9d)', Time: '2021-04-24T00:50:02-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd8c41030-634e-462a-b4b5-13305d11f0d8'	System	24 Apr 2021 04:50:12
User entered 'No (N)'	System	24 Apr 2021 04:50:12

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (cf934bbf84e46c9d)', Time: '2021-04-24T00:50:04-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd8c41030-634e-462a-b4b5-13305d11f0d8'	System	24 Apr 2021 04:50:12
User entered 'No (N)'	System	24 Apr 2021 04:50:12

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cf934bbf84e46c9d)', Time: '2021-04-24T00:50:07-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'd8c41030-634e-462a-b4b5-13305d11f0d8'	System	24 Apr 2021 04:50:12
User entered '24 Apr 2021 00:50:07'	System	24 Apr 2021 04:50:12

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[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 (cf934bbf84e46c9d)', Time: '2021-05-01T00:07:00-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '65035a2f-d574-4c0f-ae03-551598ac6e69'	System	01 May 2021 04:58:14
User entered 'No (N)'	System	01 May 2021 04:58:14

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

Have you been exposed to someone with 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 (cf934bbf84e46c9d)', Time: '2021-05-01T00:07:03-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '65035a2f-d574-4c0f-ae03-551598ac6e69'	System	01 May 2021 04:58:14
User entered 'No (N)'	System	01 May 2021 04:58:14

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cf934bbf84e46c9d)', Time: '2021-05-01T00:07:06-04:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: '65035a2f-d574-4c0f-ae03-551598ac6e69'	System	01 May 2021 04:58:14
User entered '01 May 2021 00:07:06'	System	01 May 2021 04:58:14

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:53:43

**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 18:53:43



**US3172360**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:53:43
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 18:53:43

US3172360

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:05:52

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 21:56:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-03-01T06:11:32-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ac725670-9c93-4cdd-9f80-a1e3d550aced'	System	01 Mar 2021 11:11:45
User entered 'No (N)'	System	01 Mar 2021 11:11:45

**US3172360**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:56:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (65c0baceb67112c1)', Time: '2021-03-01T06:11:41-05:00', User OID: 'PatientReportedOutcome (US3172360)', ODM File OID: 'ac725670-9c93-4cdd-9f80-a1e3d550aced' User entered '01 Mar 2021 06:11:41'	System	01 Mar 2021 11:11:45
	System	01 Mar 2021 11:11:45

**US3172360**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:41:47

**US3172360**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered '17 Nov 2020'	Mariete Rendon (b) (4)	18 Nov 2020 14:41:47
	(b) (4)	

**US3172360**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:41:47

US3172360

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:41:47

US3172360

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:41:55



**US3172360**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:29:58
User entered 'I'	System	18 Nov 2020 14:41:55

**US3172360**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Dec 2020 17:15:29

**US3172360**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '21 Dec 2020'	Jessie Downs (b) (4) (b) (4)	21 Dec 2020 17:15:29

**US3172360**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	21 Dec 2020 17:15:29

US3172360

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Dec 2020 17:15:29

US3172360

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Dec 2020 17:16:04

**US3172360**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User entered 'I'	System	21 Dec 2020 17:16:04

**US3172360**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:19:39



**US3172360**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered '19 Jan 2021'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:19:39

**US3172360**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:19:39

US3172360

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:19:39

US3172360

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:19:43

**US3172360**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User entered 'I'	System	20 Jan 2021 16:19:43

**US3172360**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:13:30

**US3172360**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:13:30

**US3172360**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:13:30



**US3172360**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'missed open label'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:13:30

**US3172360**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:13:45

**US3172360**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:47:44
User entered 'I'	System	26 Feb 2021 19:13:45

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:40:11

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '23 Mar 2021'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:40:11

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:40:11

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User entered 'VISIT4'	System	24 Mar 2021 19:40:11

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35



US3172360

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '23 Mar 2021'	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '08:25'	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User entered '23 Mar 2021 08:25'	System	31 Mar 2021 15:14:35

US3172360

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '36.7' C	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '67'	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User entered 'bpm'	System	31 Mar 2021 15:14:35



**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '13'	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User entered 'breaths/min'	System	31 Mar 2021 15:14:35

US3172360

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '104'	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User entered 'mmHg'	System	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '70'	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User entered 'mmHg'	System	31 Mar 2021 15:14:35

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43



US3172360

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:40:23

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:05:52**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:40:23

US3172360

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:32
User closed query 'Per GCL LAB Recon: Immunogenicity: GCL has an 23MAR2021 sample Barcode# 1F602873599 labelled as OL-D57. Per CCG, If Visit 4 DAY 209 and OL-D57 was performed on the same day then, OL-phase sample is collected but Immunogenicity form is updated under both the visit as yes. Please confirm if the Visit 4Day209 and OL-D57 are overlapping visit then update the Immunogenicity data under OL-D57 visit or else confirm the correct visit label if the visits are not overlapping. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Kutner (b) (4) (b) (4)	29 Apr 2021 07:32:43 22 Apr 2021 16:33:20
Query 'Per GCL LAB Recon: Immunogenicity: GCL has an 23MAR2021 sample Barcode# 1F602873599 labelled as OL-D57. Per CCG, If Visit 4 DAY 209 and OL-D57 was performed on the same day then, OL-phase sample is collected but Immunogenicity form is updated under both the visit as yes. Please confirm if the Visit 4Day209 and OL-D57 are overlapping visit then update the Immunogenicity data under OL-D57 visit or else confirm the correct visit label if the visits are not overlapping. Thank you.' answered with 'Visit was not performed because subject had first dose of MRNA 27AUG2020 and second dose of MRNA 28JAN2020. Subject came for Visit Day 209 for a follow up on 23MAR2020. Therefore, Day 57 visit is not required. ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	21 Apr 2021 20:28:35

US3172360

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB Recon: Immunogenicity: GCL has an 23MAR2021 sample Barcode# 1F602873599 labelled as OL-D57. Per CCG, If Visit 4 DAY 209 and OL-D57 was performed on the same day then, OL-phase sample is collected but Immunogenicity form is updated under both the visit as yes. Please confirm if the Visit 4Day209 and OL-D57 are overlapping visit then update the Immunogenicity data under OL-D57 visit or else confirm the correct visit label if the visits are not overlapping. Thank you.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)          Jessie Downs (b) (4) (b) (4)	16 Apr 2021 07:54:35          24 Mar 2021 19:40:47

US3172360

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '23 Mar 2021'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:40:47

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '09:53'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:40:47

**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:30:32
User entered '23 Mar 2021 09:53'	System	24 Mar 2021 19:40:47

US3172360

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:40:51



**US3172360**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:25:43
User entered 'I'	System	24 Mar 2021 19:40:51

**US3172360**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Apr 2021 12:23:45

**US3172360**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered '20 Apr 2021'	Jessie Downs (b) (4) (b) (4)	21 Apr 2021 12:23:45

**US3172360**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	21 Apr 2021 12:23:45

**US3172360**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Apr 2021 12:23:45

US3172360

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Apr 2021 12:23:32

**US3172360**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 12:23:32

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:19:35



**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered '28 Jan 2021'	Jessie Downs (b) (4)	29 Jan 2021 15:19:35
	(b) (4)	

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[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 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4)	29 Jan 2021 15:19:35
	(b) (4)	

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 15:19:35

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User closed query 'Sponsor Review: Per IRT, this subject received mRNA for Day 1 Dosing. Please update data or else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:39:36
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:20
	(b) (4)	
Query 'Sponsor Review: Per IRT, this subject received mRNA for Day 1 Dosing. Please update data or else clarify. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	21 Apr 2021 12:23:00
	(b) (4)	
User entered '06 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	21 Apr 2021 12:22:51
	(b) (4)	
User opened query 'Sponsor Review: Per IRT, this subject received mRNA for Day 1 Dosing. Please update data or else clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 18:40:37
User closed query 'Sponsor Review: Per IRT, this subject received mRNA for Day 1 Dosing. Please update data or else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:20:31
Query 'Sponsor Review: Per IRT, this subject received mRNA for Day 1 Dosing. Please update data or else clarify.' answered with 'Data updated.' (Site from DM).	Jessie Downs (b) (4)	08 Apr 2021 15:52:06
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
	(b) (4)	
User entered '22 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
	(b) (4)	
User opened query 'Sponsor Review: Per IRT, this subject received mRNA for Day 1 Dosing. Please update data or else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:14:49
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered '06 Jan 2021'	Jessie Downs (b) (4)	29 Jan 2021 15:20:00
	(b) (4)	

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:20
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:44:42

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	29 Jan 2021 15:20:00
	(b) (4)	

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:20
User closed query ' 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.	(b) (4), (b) (6)	15 Apr 2021 20:20:21
' (Site from DM). Query ' 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.	Jessie Downs (b) (4)	12 Apr 2021 15:48:55
' answered with 'Data was updated.' (Site from DM). User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error User opened query ' 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.	Jessie Downs (b) (4)	12 Apr 2021 15:48:40
	(b) (4), (b) (6)	09 Apr 2021 22:07:40
' (Site from DM). User entered 'Amendment 5 (Amendment 5)' Amendment Manager inserted this DataPoint.	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
	System	06 Mar 2021 17:44:42

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered '28 Jan 2021'	Jessie Downs (b) (4)	29 Jan 2021 15:20:00
	(b) (4)	



US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:20
	(b) (4)	
User closed query 'Sponsor Review: Per IRT this subject was randomized to mRNA treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:20:17
Query 'Sponsor Review: Per IRT this subject was randomized to mRNA treatment assignment. Please review and reconcile.' answered with 'Data updated.' (Site from DM).	Jessie Downs (b) (4)	08 Apr 2021 15:52:09
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
	(b) (4)	
User opened query 'Sponsor Review: Per IRT this subject was randomized to mRNA treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:28:35
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4)	29 Jan 2021 15:20:00
	(b) (4)	

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
User opened query 'Dose 1 says not administered but per IRT mRNA was administered, please update accordingly ' (Site from CRA).	(b) (4), (b) (6)	04 May 2021 01:30:53
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:20
Signature has been broken.	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4)	29 Jan 2021 15:20:00

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:20
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
	(b) (4)	
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Jessie Downs (b) (4)	08 Apr 2021 15:51:56
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4)	29 Jan 2021 15:20:00
	(b) (4)	

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	29 Jan 2021 15:20:00
	(b) (4)	

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'I'	System	29 Jan 2021 15:20:00

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 19:48:41
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'I'	System	29 Jan 2021 15:20:00

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:05:52**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:05:52**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14



**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:05:52**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	29 Jan 2021 15:23:14
DataPoint set to visible.	System	29 Jan 2021 15:20:00

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:05:52**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:05:52**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	29 Jan 2021 15:23:14
DataPoint set to visible.	System	29 Jan 2021 15:20:00

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '28 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered '08:52'	Jessie Downs (b) (4)	29 Jan 2021 15:23:14
	(b) (4)	



**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '28 Jan 2021 08:52'	System	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '65'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'bpm'	System	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '17'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'breaths/min'	System	29 Jan 2021 15:23:14



US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '108'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'mmHg'	System	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '68'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'mmHg'	System	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:05:52**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:05:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	29 Jan 2021 15:23:14
DataPoint set to visible.	System	29 Jan 2021 15:20:00

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14



US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '28 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '11:15'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '28 Jan 2021 11:15'	System	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '83'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14



**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'bpm'	System	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '17'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'breaths/min'	System	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '126'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'mmHg'	System	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '84'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:23:14

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'mmHg'	System	29 Jan 2021 15:23:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:20:14



**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:05:52**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '28 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:20:14

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:57

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:52

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '28 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:57

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Urine (URINE)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:57

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Negative (NEGATIVE)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:57

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:57

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:57

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:57



**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered empty.	System	29 Jan 2021 15:21:57

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:31

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:31

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

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 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	29 Jan 2021 15:21:31
	(b) (4)	

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'mRNA-1273'	System	29 Jan 2021 15:21:31
DataPoint set to visible.	System	29 Jan 2021 15:20:00

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered '28 Jan 2021'	Jessie Downs (b) (4)	29 Jan 2021 15:21:31
	(b) (4)	

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '10:45'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:31

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '28 Jan 2021 10:45'	System	29 Jan 2021 15:21:31



US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:31

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'ONCE'	System	29 Jan 2021 15:21:31

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'INTRAMUSCULAR'	System	29 Jan 2021 15:21:31

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:20:43

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '28 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:20:43

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '10:35'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:20:43

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '28 Jan 2021 10:35'	System	29 Jan 2021 15:20:43

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:20:58



**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:05:52**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '28 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:20:58

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:05:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '10:37'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:20:58

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:05:52**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered '28 Jan 2021 10:37'	System	29 Jan 2021 15:20:58

US3172360

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 15:21:02

**US3172360**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:34:40
User entered 'I'	System	29 Jan 2021 15:21:02

**US3172360**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	06 Feb 2021 15:00:04
	(b) (4)	

US3172360

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered '05 Feb 2021'	Jessie Downs (b) (4)	06 Feb 2021 15:00:04
	(b) (4)	

**US3172360**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	06 Feb 2021 15:00:04
	(b) (4)	



US3172360

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	06 Feb 2021 15:00:04
	(b) (4)	

**US3172360**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:49
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	06 Feb 2021 15:01:04
	(b) (4)	

**US3172360**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User entered 'I'	System	06 Feb 2021 15:01:04

**US3172360**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User entered 'I'	System	06 Feb 2021 15:01:04
DataPoint set to visible.	System	06 Feb 2021 15:01:04

**US3172360**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:25

**US3172360**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered '26 Feb 2021'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:25

US3172360

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:25

**US3172360**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'OLD29'	System	26 Feb 2021 19:10:25



**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4)	26 Feb 2021 19:12:35
	(b) (4)	

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 14:00:41
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	26 Feb 2021 19:12:35
	(b) (4)	

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered '09:06'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered '26 Feb 2021 09:06'	System	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered '36.4' C	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35



**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered '61'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'bpm'	System	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered '14'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'breaths/min'	System	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered '119'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'mmHg'	System	26 Feb 2021 19:12:35

US3172360

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered '72'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'mmHg'	System	26 Feb 2021 19:12:35



**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 14:00:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	26 Feb 2021 19:12:35
	(b) (4)	

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	26 Feb 2021 19:12:35

US3172360

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

US3172360

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35



**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	26 Feb 2021 19:12:35

US3172360

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	26 Feb 2021 19:12:35

US3172360

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:12:35

**US3172360**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	26 Feb 2021 19:12:35



**US3172360**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:05:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:37

**US3172360**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:05:52**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 14:00:41
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	26 Feb 2021 19:10:37
	(b) (4)	

**US3172360**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:50

**US3172360**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered '26 Feb 2021'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:50

**US3172360**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 14:00:41
	(b) (4)	
User entered 'Urine (URINE)'	Jessie Downs (b) (4)	26 Feb 2021 19:10:50
	(b) (4)	

**US3172360**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'Negative (NEGATIVE)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:50

**US3172360**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:50

**US3172360**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:50



**US3172360**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:10:50

**US3172360**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:05:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	26 Feb 2021 19:10:50

**US3172360**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:41:26

US3172360

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:20
	(b) (4)	
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		24 Mar 2021 19:43:25
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jessie Downs (b) (4)	24 Mar 2021 19:43:25
	(b) (4)	
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	24 Mar 2021 19:41:26
User entered empty.	Jessie Downs (b) (4)	24 Mar 2021 19:41:26
	(b) (4)	

US3172360

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

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)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:20
	(b) (4)	
User entered 'subject did not dose on Day 29 visit, they received one dose of MRNA in part A and second dose on decision visit.' reason for change: Data Entry Error	Jessie Downs (b) (4)	24 Mar 2021 19:43:25
User entered empty.	Jessie Downs (b) (4)	24 Mar 2021 19:41:26
	(b) (4)	

**US3172360**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	24 Mar 2021 19:41:26
DataPoint set to visible.	System	06 Feb 2021 15:01:04

US3172360

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:41:26

**US3172360**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:41:26



**US3172360**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	24 Mar 2021 19:41:26

**US3172360**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:41:26

US3172360

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	24 Mar 2021 19:41:26

**US3172360**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:52**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered empty.	System	24 Mar 2021 19:41:26

**US3172360**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:00:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 19:11:28

**US3172360**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'I'	System	26 Feb 2021 19:11:28

**US3172360**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:49:13

**US3172360**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:49:13



**US3172360**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:49:13

**US3172360**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'missed'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:49:13

US3172360

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:49:18

**US3172360**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 19:49:18

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:05:52**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Sep 2020 18:57:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	14 Sep 2020 14:22:53
	(b) (4)	

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 06:59:23
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 06:59:23
	(b) (4)	
Data point term sent to Coder	System	29 Sep 2020 20:50:48
Coding entries removed.	Jessie Downs (b) (4)	29 Sep 2020 20:50:15
	(b) (4)	
User entered 'PSORIASIS FLARE' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Sep 2020 20:50:15
	(b) (4)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 19:05:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 19:05:38
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 19:04:11
User entered 'PSORIASIS'	Mariete Rendon (b) (4)	22 Sep 2020 19:03:47
	(b) (4)	

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47



**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	29 Sep 2020 21:38:44
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	29 Sep 2020 21:38:44
User entered '20 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Sep 2020 21:38:44
	(b) (4)	
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	29 Sep 2020 19:09:26
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	29 Sep 2020 19:09:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 19:09:26
User entered '20 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Sep 2020 19:09:26
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 19:03:47
User entered 'UN Aug 2020' (non-conformant).	Mariete Rendon (b) (4)	22 Sep 2020 19:03:47
	(b) (4)	

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	18 Nov 2020 14:40:04
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	22 Sep 2020 19:03:47
	(b) (4)	

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered '17 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	18 Nov 2020 14:40:04
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	22 Sep 2020 19:03:47
	(b) (4)	

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 19:03:47



**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:04:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 19:04:07
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Sep 2020 19:04:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:03:47
User entered empty.	Mariete Rendon (b) (4)	22 Sep 2020 19:03:47
	(b) (4)	

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47



**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Related (RELATED)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 19:19:49
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Subject was not dosed due to Adverse Event Psoriasis Flare' (Site from System).	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 20:49:50
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:05:28
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#9) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:02:15
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#9) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	09 Dec 2020 16:46:18
User entered '0' reason for change: Data Entry Error	(b) (4)	09 Dec 2020 16:45:47
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#9) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:38:09
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		22 Sep 2020 19:04:07
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	22 Sep 2020 19:03:47
User entered '1'	Mariete Rendon (b) (4)	22 Sep 2020 19:03:47
	(b) (4)	



US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	09 Dec 2020 16:45:47
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Sep 2020 19:04:07
	(b) (4)	
User entered '1'	Mariete Rendon (b) (4)	22 Sep 2020 19:03:47
	(b) (4)	

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

US3172360

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:40:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:03:47

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 19:04:07

**US3172360**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 19:03:47

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:05:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:33:09



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:35:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:35:37
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 15:34:29
User entered 'XANAX'	Jessie Downs (b) (4)	28 Aug 2020 15:34:13
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'INSOMNIA'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '1'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'UN UNK 2018'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:38:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 15:38:22
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Aug 2020 15:38:22
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:34:13
User entered empty.	Jessie Downs (b) (4)	28 Aug 2020 15:34:13
	(b) (4)	

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 15:34:13



**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 15:34:13

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 15:34:13

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE, PRODUCTSYNONYM: OLZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:36:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:36:40
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 15:35:30
User entered 'OLZAPINE'	Jessie Downs (b) (4)	28 Aug 2020 15:34:56
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'INSOMNIA'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '30'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'UN UNK 2018'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:34:56



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:38:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 15:38:32
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Aug 2020 15:38:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:34:56
User entered empty.	Jessie Downs (b) (4)	28 Aug 2020 15:34:56
	(b) (4)	

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 15:34:56

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 15:34:56

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 15:34:56

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DEPAKOTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:37:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:37:45
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 15:36:34
User entered 'DEPAKOTE'	Jessie Downs (b) (4)	28 Aug 2020 15:36:05
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'BIPOLAR'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '500'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:05:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'UN UNK 2018'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05



**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:05:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:38:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 15:38:45
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Aug 2020 15:38:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:36:05
User entered empty.	Jessie Downs (b) (4)	28 Aug 2020 15:36:05
	(b) (4)	

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:05:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 15:36:05

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 15:36:05

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 15:36:05

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:38:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:38:49
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 15:37:36
User entered 'ALBUTEROL'	Jessie Downs (b) (4)	28 Aug 2020 15:37:10
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. '(Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:20:41
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Condition is recorded in Medical History' (Site from DM).	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 15:04:18
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. '(Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:00:33
User entered 'ASTHMA'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:05:52**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '90'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM). Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'Data was updated' (Site from DM).	(b) (4), (b) (6) Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:20:44 30 Sep 2020 15:03:13
User entered 'ug (ug)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 15:02:42
User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM). User entered 'Other (OTHER)'	(b) (4), (b) (6) Jessie Downs (b) (4) (b) (4)	30 Sep 2020 09:00:41 28 Aug 2020 15:37:10

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	30 Sep 2020 15:02:42
	(b) (4)	
User entered 'MCG'	Jessie Downs (b) (4)	28 Aug 2020 15:37:10
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10

US3172360

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:05:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'UN UNK 2000'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:37:10

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:39:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 15:39:00
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Aug 2020 15:39:00
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:37:10
User entered empty.	Jessie Downs (b) (4)	28 Aug 2020 15:37:10
	(b) (4)	

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:05:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:37:10

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:37:10

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:37:10



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 00:20:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 00:20:30
Data point term sent to Coder	System	16 Oct 2020 22:03:50
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 22:03:02
User entered 'EXCEDRIN - (ACETAMINOPHEN 250 MG) (ASPIRIN 250 MG) (CAFFEINE 65 MG)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 22:03:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 20:32:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 20:32:55
Data point term sent to Coder	System	02 Oct 2020 20:31:29
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:30:42
User entered 'EXCEDRIN' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:30:42

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:50:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:50:43
Data point term sent to Coder	System	08 Sep 2020 14:26:15
User closed query 'CDM-Coding: For Coding Purpose, Please update the medication by providing the active/generic ingredients.' (Site from System).	System	08 Sep 2020 14:26:04
Query 'CDM-Coding: For Coding Purpose, Please update the medication by providing the active/generic ingredients.' answered with 'Data updated' (Site from System).	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 14:26:04
User entered 'EXCEDRIN (ACETAMINOPHEN 250 MG, ASPIRIN 250 MG, CAFFEINE 65 MG)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 14:25:51
User opened query 'CDM-Coding: For Coding Purpose, Please update the medication by providing the active/generic ingredients.' (Site from System).	Coder Import (b) (4) (b) (4)	01 Sep 2020 09:16:39
Data point term sent to Coder	System	28 Aug 2020 15:38:37
User entered 'EXCEDRIN'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:05:52**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'MIGRAINE'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User closed query 'Per DM CLR RQ: Response noted, however, kindly note that the combined dosage strengths should be recorded in the Dose field. Please update the dose to include all components as applicable. Else, provide a comment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:02:10
Query 'Per DM CLR RQ: Response noted, however, kindly note that the combined dosage strengths should be recorded in the Dose field. Please update the dose to include all components as applicable. Else, provide a comment.' answered with 'Data updated' (Site from DM).	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 22:03:24
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 22:03:02
User opened query 'Per DM CLR RQ: Response noted, however, kindly note that the combined dosage strengths should be recorded in the Dose field. Please update the dose to include all components as applicable. Else, provide a comment.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:12:09
User closed query 'Per DM CLR: Please review if this is a combination drug; note, only one component has been recorded. Please update the dose to include all components.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:21:01
Query 'Per DM CLR: Please review if this is a combination drug; note, only one component has been recorded. Please update the dose to include all components.' answered with 'Components were separated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:34:30
User opened query 'Per DM CLR: Please review if this is a combination drug; note, only one component has been recorded. Please update the dose to include all components.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 03:20:17
User entered '250'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered 'tablet (TABLET)' reason for change:	Jessie Downs (b) (4)	16 Oct 2020 22:03:02
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	28 Aug 2020 15:38:01
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:05:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:05:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'UN UNK 2020'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:38:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 15:38:05
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Aug 2020 15:38:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:38:01
User entered empty.	Jessie Downs (b) (4)	28 Aug 2020 15:38:01
	(b) (4)	



**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:05:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:38:01

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:38:01

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 15:38:01

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 20:33:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 20:33:44
Data point term sent to Coder	System	02 Oct 2020 20:32:31
User entered 'ACETAMINOPHEN'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:05:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'MIGRAINE'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '250'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'UN UNK 2020'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:05:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:05:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:07

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:05:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:32:07

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:32:07

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:32:07

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:35:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:35:49
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 20:34:36
Data point term sent to Coder	System	02 Oct 2020 20:33:31
User entered 'ASPIRIN'	Jessie Downs (b) (4)	02 Oct 2020 20:32:55
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 20:34:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 20:34:03
User entered 'MIGRAINE' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Oct 2020 20:34:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 20:32:55
User entered empty.	Jessie Downs (b) (4)	02 Oct 2020 20:32:55
	(b) (4)	



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '250'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:05:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'UN UNK 2020'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:05:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:05:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:32:55

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:05:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:32:55

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:32:55

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:32:55

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: XANTHINE DERIVATIVES, PRODUCT: CAFFEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:35:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:35:49
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 20:34:34
User entered 'CAFFEINE'	Jessie Downs (b) (4)	02 Oct 2020 20:33:45
	(b) (4)	



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'MIGRAINE'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '65'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:05:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'UN UNK 2020'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:05:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:05:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 20:33:45

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:05:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:33:45

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:33:45



**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:33:45

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE, PRODUCTSYNONYM: CLOBETAZOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 10:03:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 10:03:01
	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 14:35:10
User entered 'clobetazol cream'	Mariete Rendon (b) (4)	18 Nov 2020 14:35:02
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'psoriasis'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User closed query 'Per DM CLR: Please provide the drug strength/preparation in the Drug Name field (e.g. Betamethasone 0.025%) and consider if the # of APPLICATION (in total daily dose) in the dose/unit fields would be a more appropriate response. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:13:06
Query 'Per DM CLR: Please provide the drug strength/preparation in the Drug Name field (e.g. Betamethasone 0.025%) and consider if the # of APPLICATION (in total daily dose) in the dose/unit fields would be a more appropriate response. Reconcile and update as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	18 Dec 2020 19:14:22
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	18 Dec 2020 19:14:02
	(b) (4)	
User opened query 'Per DM CLR: Please provide the drug strength/preparation in the Drug Name field (e.g. Betamethasone 0.025%) and consider if the # of APPLICATION (in total daily dose) in the dose/unit fields would be a more appropriate response. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:46:43
User entered '0.05'	Mariete Rendon (b) (4)	18 Nov 2020 14:35:02
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Other (OTHER)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:35:40
	(b) (4)	
User entered 'application' reason for change: Data Entry Error	Jessie Downs (b) (4)	18 Dec 2020 19:14:02
	(b) (4)	
User entered '%'	Mariete Rendon (b) (4)	18 Nov 2020 14:35:02
	(b) (4)	

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02



US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Topical (TOPICAL)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '25 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02

US3172360

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:05:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 14:35:02



**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 14:35:02

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 14:35:02

**US3172360**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:05:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 14:35:02

US3172360

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:05:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	08 Sep 2020 14:04:02

**US3172360**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:05:52**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:24:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:05:28

US3172360

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:52

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:24:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User closed query 'Per CDM: reason for discontinuation is based PI decision relating to an AE. Please consider selecting AE (Specify) and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:39:58
Query 'Per CDM: reason for discontinuation is based PI decision relating to an AE. Please consider selecting AE (Specify) and make all applicable updates.' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 20:52:57
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 20:52:40
User opened query 'Per CDM: reason for discontinuation is based PI decision relating to an AE. Please consider selecting AE (Specify) and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:27:55
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:05:28

US3172360

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:52

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:24:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:35:40
User closed query 'Per CDM: Please update with AE log line #' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:26:33
Query 'Per CDM: Please update with AE log line #' answered with 'Data updated as per query request' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 19:33:28
User entered 'A/E #1' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 19:33:13
User opened query 'Per CDM: Please update with AE log line #' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:40:55
User entered 'DUE TO A/E'	Mariete Rendon (b) (4) (b) (4)	22 Sep 2020 19:05:28