

US3512272 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:58:23

All time stamps listed in this document are displayed in GMT

US3512272

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 22:26:03

Generated On: 10 Jun 2021 07:58:23

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[Participant ID](#)

US3512272

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

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US3512272

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Date of Informed Consent ( <i>dd MMM yyyy</i> )	17 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	ALLERGY TO ASPIRIN
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	ALLERGY TO MANGO
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	COLON POLYPS
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	FIBROIDS
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	FARSIGHTED
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	OVERWEIGHT
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	NECK 7TH DISC INJURY
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	BENIGN LUMP OF RIGHT BREAST
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	REMOVAL OF BENIGN RIGHT BREAST LUMP
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	LEFT KNEE INJURY
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	LEFT KNEE RECONSTRUCTION
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Condition	VITAMIN D DEFICIENCY
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)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	17 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	12:07 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 12:07
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	260 lb
BMI ( <i>xxx.x</i> )	42.05284 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 22:26:04

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Date of assessment (dd MMM yyyy) 17 SEP 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) UN UNK 2007

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:26:04

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	True
<b>Specify</b>	WORKS AT LEAST 5 DAYS/WEEK; INTERACTS W/>5 PEOPLE DAILY; HAS ATTENDED LARGE GROUP EVENTS IN THE PAST FEW WEEKS (CHURCH); PLANS ON ROUTINELY GOING TO PLACES WHERE PEOPLE GATHER

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 145899

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

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)	17 SEP 2020
Time of assessment (00:00-23:59)	12:07 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 12:07
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

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)	17 SEP 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 13:45
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:26:05

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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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 13:14 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 13:14

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	12:45 (24 HR)
Collection date and time (derived)	17 SEP 2020 12:45

US3512272

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:28	17 SEP 2020 12:28
Nasopharyngeal Swab 2	No		

US3512272

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

17 SEP 2020 13:49

PC Open Date & Time

17 SEP 2020 13:34

PC Close Date & Time

17 SEP 2020 16:04

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 17 SEP 2020 19:57

PC Open Date & Time 17 SEP 2020 16:59

PC Close Date & Time 18 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

18 SEP 2020 18:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 19:09

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**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 96.5 °F

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

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

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

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

PC Time Stamp 20 SEP 2020 18:30

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59



US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 19:45

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

22 SEP 2020 21:08

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 21:22

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 13:50

PC Open Date & Time

17 SEP 2020 13:34

PC Close Date & Time

17 SEP 2020 16:04

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**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

17 SEP 2020 19:58

PC Open Date & Time

17 SEP 2020 16:59

PC Close Date & Time

18 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**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

18 SEP 2020 18:56

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**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

19 SEP 2020 19:10

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**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

20 SEP 2020 18:31

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**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

21 SEP 2020 19:45

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**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

22 SEP 2020 21:09

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**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

23 SEP 2020 21:23

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**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 ☐

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 13:51
PC Open Date & Time	17 SEP 2020 13:34
PC Close Date & Time	17 SEP 2020 16:04

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**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 ☐

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 19:59
PC Open Date & Time	17 SEP 2020 16:59
PC Close Date & Time	18 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**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 ☒



US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 18:57
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 18:33
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 19:46
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

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 ☒



US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 21:10
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 21:24
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 24 SEP 2020 14:30

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3512272

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 07:58:23

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 14:30
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3512272

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512272

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3512272

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512272

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT2

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

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)	15 OCT 2020
Time of assessment (00:00-23:59)	15:24 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 15:24
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	16:58 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 16:58
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	175 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3512272

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3512272

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 16:27 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 16:27

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



US3512272

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	15:53 (24 HR)
Collection date and time (derived)	15 OCT 2020 15:53

US3512272

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:30	15 OCT 2020 15:30
Nasopharyngeal Swab 2	No		

US3512272

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 16:58

PC Open Date & Time

15 OCT 2020 16:47

PC Close Date & Time

15 OCT 2020 19:17

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

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

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

PC Time Stamp 15 OCT 2020 21:01

PC Open Date & Time 15 OCT 2020 20:12

PC Close Date & Time 16 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	16 OCT 2020 21:50
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 20:19

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 19:30

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59



US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 20:14

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 20:04

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 23:37

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**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

15 OCT 2020 16:58

PC Open Date & Time

15 OCT 2020 16:47

PC Close Date & Time

15 OCT 2020 19:17

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**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

15 OCT 2020 21:02

PC Open Date & Time

15 OCT 2020 20:12

PC Close Date & Time

16 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**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

16 OCT 2020 21:52

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**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

17 OCT 2020 20:20

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**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

18 OCT 2020 19:31

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59



US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**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

19 OCT 2020 20:14

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**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

20 OCT 2020 20:05

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**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

21 OCT 2020 23:38

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**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 ☐

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 16:59
PC Open Date & Time	15 OCT 2020 16:47
PC Close Date & Time	15 OCT 2020 19:17

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**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 ☐

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 21:03
PC Open Date & Time	15 OCT 2020 20:12
PC Close Date & Time	16 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 21:55
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**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

EAB) (1725)

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US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 20:21
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:32
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**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

EAB) (1725)

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US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 20:15
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

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

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**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 ☒

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 23:39
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3512272

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512272

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512272

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3512272

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 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

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	13:30 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 13:30
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	78 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512272

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

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.*

US3512272

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

15:42 (24 HR)

Collection date and time (derived)

12 NOV 2020 15:42

US3512272

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:05

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 04:46:42

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	25 NOV 2020 16:29:13
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59



US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 75

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

No ☒

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

02 DEC 2020 14:25:09

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 DEC 2020 22:00:02
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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	23 DEC 2020 15:59:52
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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

30 DEC 2020 18:10:55

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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

16 JAN 2021 22:21:27

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 11:53:15

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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

03 FEB 2021 20:47:58

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 FEB 2021 14:18:49
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

<b>TIMEPOINT</b>	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 FEB 2021 16:35:28
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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27 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 MAR 2021 23:15:23
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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

17 MAR 2021 16:17:05

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 18:26:48

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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



US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 201

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

No ☒

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 APR 2021 15:37:48

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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

14 APR 2021 08:46:04

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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

28 APR 2021 20:56:50

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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="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"/>



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2021 23:59
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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	09 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59
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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59
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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59
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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 NOV 2021 23:59
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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐ 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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 467

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐  
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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 530

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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23 MAR 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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13 APR 2022 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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°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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

**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 ☐

**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

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US3512272

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

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"/>



**US3512272**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2022 23:59

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**US3512272**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 07:58:23**

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		04 MAR 2021 07:27:14

US3512272

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512272

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512272

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512272

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:26:04

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3512272

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 12:54:27

Generated On: 10 Jun 2021 07:58:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512272

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 12:54:25

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512272

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 16:46:34

Generated On: 10 Jun 2021 07:58:23

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

Visit date (dd MMM yyyy)	13 APR 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
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US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 16:46:34

Generated On: 10 Jun 2021 07:58:23

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3512272

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 16:46:34

Generated On: 10 Jun 2021 07:58:23

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.*

US3512272

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 16:46:34

Generated On: 10 Jun 2021 07:58:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 APR 2021
Collection time (00:00-23:59)	15:36 (24 HR)
Collection date and time (derived)	13 APR 2021 15:36

US3512272

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 16:46:34

Generated On: 10 Jun 2021 07:58:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3512272**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

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*



**US3512272**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3512272

Folder: Covid-19 Assessment (2)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:58:23

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"/>

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Data signed: (b) (4) 19 Mar 2021 20:46:09

Generated On: 10 Jun 2021 07:58:23

Date of Contact	11 MAR 2021
Time of Contact	13:06
Date and Time of Contact (derived)	11 MAR 2021 13:06
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	3 MAR 2021
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	4 MAR 2021
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	5 MAR 2021
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	6 MAR 2021
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	7 MAR 2021
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	8 MAR 2021
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	9 MAR 2021
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (8)

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Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 MAR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 MAR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

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Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 MAR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3512272

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 MAR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 MAR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 MAR 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 MAR 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 MAR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.5 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 MAR 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 MAR 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 MAR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	95.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Date of Visit	15 MAR 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	15 MAR 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	THE LEGENDS CENTER JACKSONVILLE
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3512272

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	17 MAR 2021
Day 5	Yes	19 MAR 2021
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3512272

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 20:46:10

Generated On: 10 Jun 2021 07:58:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	SICKD1

US3512272

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 20:46:10

Generated On: 10 Jun 2021 07:58:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	15:33 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 15:33
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	260 lb
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	83 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3512272

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 20:46:10

Generated On: 10 Jun 2021 07:58:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3512272

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Mar 2021 20:46:10

Generated On: 10 Jun 2021 07:58:23

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 MAR 2021

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

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 SICKD28

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

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.*

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Mar 2021 14:27:27

Generated On: 10 Jun 2021 07:58:23

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3512272

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:26:03

Generated On: 10 Jun 2021 07:58:23

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

Visit date (dd MMM yyyy)	28 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3512272

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

Form: Unblinding

Data signed: (b) (4) 14 Apr 2021 16:46:34

Generated On: 10 Jun 2021 07:58:23

Date of updated informed consent (dd MMM yyyy) 28 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 28 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_



US3512272

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:26:03

Generated On: 10 Jun 2021 07:58:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

15:31 (24 HR)

Collection date and time (derived)

28 JAN 2021 15:31

US3512272

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 22:26:03

Generated On: 10 Jun 2021 07:58:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	15:21
Collection Date and Time (derived)	28 JAN 2021 15:21

US3512272

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 22:26:03

Generated On: 10 Jun 2021 07:58:23

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3512272

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

AEID	
Adverse event	WORSENING HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	9 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3512272

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

AEID	
Adverse event	WORSENING HYPERCHOLESTEROLEMIA
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input checked="" type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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)	

US3512272

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

AEID	
Adverse event	COVID LIKE ILLNESS
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)	3 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

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

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 22:26:03

Generated On: 10 Jun 2021 07:58:23

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

Yes ☒

No ☐

---

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

---

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication AMLODIPINE BENAZAPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	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)		9 DEC 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 80

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	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 1987
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication METOPROLOL ER SUCCINATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	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 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication	VITAMIN B COMPLEX: THIAMINE HCL 5MG RIBOFLAVIN 5-PHOSPOHATE 10 MG NIACINAMIDE 30MG PYRIDOXAL-5 PHOSPHATE 10 MG B9 680MCG B12 24MCG B7 60MCG B5 10 MG
--------------------	--

Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
-------------	--

Indication	SUPPLEMENT
------------	------------

Dose per administration	1
-------------------------	---

Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
-----------	--

If dose unit is Other, specify

Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/>
-----------	---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	other	<input type="radio"/>
If frequency is Other, specify		
Route of administration	Oral	<input checked="" type="radio"/>
	Topical	<input type="radio"/>
	Subcutaneous	<input type="radio"/>
	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	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)	10 SEP 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE ACHES

Dose per administration 200

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	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)		20 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT THE INJECTION SITE

Dose per administration 800

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication SEASONAL INFLUENZA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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 ☐

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EAB) (1725)

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US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	Intramuscular	<input checked="" 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)		9 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication VITAMIN D2

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 DEC 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING  
HYPERCHOLESTEROLEMIA

Dose per administration 80

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication DAYQUIL (ACETAMINOPHEN  
325MG, DEXTROMETHORPHAN  
HBR 15 MG, DOXYLAMINE  
SUCCINATE 6.25 MG)

Prophylaxis Yes ☐  
No ☒

Indication COVID LIKE ILLNESS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	Transdermal	<input type="checkbox"/>
	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)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication NYQUIL ( ACETAMINOPHEN 325  
MG, DEXTROMETHORPHAN  
HBR 10 MG, PHENYLEPHRINE  
HCL 5 MG)

Prophylaxis Yes ☐  
No ☒

Indication COVID LIKE ILLNESS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	Transdermal	<input type="checkbox"/>
	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)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication COVID LIKE ILLNESS

Dose per administration 2000

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:07:21

Generated On: 10 Jun 2021 07:58:23

	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)		3 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512272

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 22:26:03

Generated On: 10 Jun 2021 07:58:23

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:58:23

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:58:23

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

US3512272 (Prod: Jacksonville Center for Clinical Research Center)



**US3512272**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 07:58:23**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'US3512272'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:39:37

US3512272

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:20:57

**US3512272**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:39:38

US3512272

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:23

[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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	17 Sep 2020 17:20:57

**US3512272**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'SCRN'	System	17 Sep 2020 17:20:57

US3512272

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:39:39

US3512272

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:23

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '61'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

**US3512272**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:58:23**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'YEARS'	System	17 Sep 2020 17:21:14



US3512272

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '61'	System	17 Sep 2020 17:21:24

**US3512272**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:58:23**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Female (F)'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

US3512272

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:23

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

**US3512272**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:58:23**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

US3512272

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:23

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'I'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

**US3512272**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:58:23**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

**US3512272**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:58:23**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

**US3512272**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:58:23**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14



US3512272

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

US3512272

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:23

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

**US3512272**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:58:23**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

**US3512272**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:58:23**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:14

US3512272

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:24

**US3512272**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Sep 2020'	System	17 Sep 2020 17:21:24

**US3512272**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2020'	System	17 Sep 2020 17:21:24

**US3512272**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:58:23**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Amendment 3 (3)'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:24



**US3512272**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:24

**US3512272**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:21:24

**US3512272**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:58:23**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:21:24

**US3512272**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:58:23**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:24

**US3512272**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:58:23**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:39:38

US3512272

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'I'	System	17 Sep 2020 17:21:29

US3512272

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:21:29

US3512272

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:58:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:25:06



US3512272

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:28:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:28:43
Data point term sent to Coder	System	17 Sep 2020 17:27:33
User entered 'ALLERGY TO ASPIRIN'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:01

**US3512272**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1974'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:01

**US3512272**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:01

**US3512272**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:01

**US3512272**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:58:23**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:27:01

**US3512272**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:01

**US3512272**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1974'	System	17 Sep 2020 17:27:01

**US3512272**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1974'	System	17 Sep 2020 17:27:01



**US3512272**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:27:01

**US3512272**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:27:01

US3512272

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:10:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:10:40
Data point term sent to Coder	System	17 Sep 2020 17:27:33
User entered 'ALLERGY TO MANGO'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:13

**US3512272**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1974'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:13

**US3512272**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:13

**US3512272**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:13

**US3512272**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:27:13

**US3512272**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:13



**US3512272**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1974'	System	17 Sep 2020 17:27:13

**US3512272**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1974'	System	17 Sep 2020 17:27:13

**US3512272**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:27:13

**US3512272**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:27:13

US3512272

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:28:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:28:43
Data point term sent to Coder	System	17 Sep 2020 17:27:33
User entered 'SEASONAL ALLERGIES'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:26

**US3512272**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1965'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:26

**US3512272**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:26

**US3512272**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:26



**US3512272**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:27:26

**US3512272**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:26

**US3512272**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1965'	System	17 Sep 2020 17:27:26

**US3512272**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1965'	System	17 Sep 2020 17:27:26

**US3512272**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:27:26

**US3512272**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:27:26

US3512272

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:29:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:29:46
Data point term sent to Coder	System	17 Sep 2020 17:28:35
User entered 'DIVERTICULOSIS'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:43

**US3512272**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2015'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:43



**US3512272**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:43

**US3512272**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:43

**US3512272**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:27:43

**US3512272**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:43

**US3512272**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2015'	System	17 Sep 2020 17:27:43

**US3512272**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2015'	System	17 Sep 2020 17:27:43

US3512272

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:27:43

**US3512272**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:27:43



US3512272

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:29:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:29:46
Data point term sent to Coder	System	17 Sep 2020 17:28:37
User entered 'COLON POLYPS'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:56

**US3512272**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2015'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:56

**US3512272**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:56

**US3512272**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:56

**US3512272**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:58:23**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2015'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:56

**US3512272**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:27:56

**US3512272**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2015'	System	17 Sep 2020 17:27:56

**US3512272**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2015'	System	17 Sep 2020 17:27:56



**US3512272**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2015'	System	17 Sep 2020 17:27:56

**US3512272**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2015'	System	17 Sep 2020 17:27:56

US3512272

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:29:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:29:46
Data point term sent to Coder	System	17 Sep 2020 17:28:37
User entered 'FIBROIDS'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:19

**US3512272**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2005'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:19

**US3512272**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:19

**US3512272**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:19

**US3512272**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2007'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:19

**US3512272**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:19



**US3512272**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2005'	System	17 Sep 2020 17:28:19

**US3512272**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2005'	System	17 Sep 2020 17:28:19

**US3512272**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2007'	System	17 Sep 2020 17:28:19

**US3512272**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2007'	System	17 Sep 2020 17:28:19

US3512272

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:29:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:29:45
Data point term sent to Coder	System	17 Sep 2020 17:28:37
User entered 'FARSIGHTED'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:32

**US3512272**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2005'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:32

**US3512272**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:32

**US3512272**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:32



**US3512272**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:28:32

**US3512272**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:28:32

**US3512272**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2005'	System	17 Sep 2020 17:28:32

**US3512272**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2005'	System	17 Sep 2020 17:28:32

**US3512272**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:28:32

**US3512272**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:28:32

US3512272

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:30:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:30:45
Data point term sent to Coder	System	17 Sep 2020 17:29:38
User entered 'HIGH CHOLESTEROL'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:08

**US3512272**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1987'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:08



**US3512272**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:08

**US3512272**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:08

**US3512272**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:58:23**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:29:08

**US3512272**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:08

**US3512272**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1987'	System	17 Sep 2020 17:29:08

**US3512272**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1987'	System	17 Sep 2020 17:29:08

**US3512272**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:29:08

**US3512272**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:29:08



US3512272

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Overweight, LLT: Overweight - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:30:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:30:45
Data point term sent to Coder	System	17 Sep 2020 17:29:39
User entered 'OVERWEIGHT'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:25

**US3512272**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2000'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:25

**US3512272**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:25

**US3512272**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:25

**US3512272**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:58:23**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:29:25

**US3512272**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:25

**US3512272**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2000'	System	17 Sep 2020 17:29:25

**US3512272**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2000'	System	17 Sep 2020 17:29:25



**US3512272**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:29:25

**US3512272**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:29:25

US3512272

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:31:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:31:47
Data point term sent to Coder	System	17 Sep 2020 17:30:40
User entered 'HYPERTENSION'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:40

**US3512272**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2000'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:40

**US3512272**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:40

**US3512272**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:40

**US3512272**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:58:23**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:29:40

**US3512272**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:29:40



**US3512272**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2000'	System	17 Sep 2020 17:29:40

**US3512272**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2000'	System	17 Sep 2020 17:29:40

**US3512272**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:29:40

**US3512272**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:29:40

US3512272

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Peripheral swelling - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:24:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:24:33
Data point term sent to Coder	System	17 Sep 2020 17:30:40
User entered 'SWELLING IN LEGS OR FEET'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:02

**US3512272**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2015'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:02

**US3512272**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:02

**US3512272**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:02



**US3512272**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:58:23**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:30:02

**US3512272**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:02

**US3512272**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2015'	System	17 Sep 2020 17:30:02

**US3512272**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2015'	System	17 Sep 2020 17:30:02

**US3512272**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:30:02

**US3512272**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	17 Sep 2020 17:30:02

US3512272

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 12:06:30
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:55:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:31:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:31:47
Data point term sent to Coder	System	17 Sep 2020 17:30:40
User entered 'BILATERAL KNEE REPLACEMENT'	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 17:30:21

**US3512272**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2013'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:21



**US3512272**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:21

**US3512272**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:21

**US3512272**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2013'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:21

**US3512272**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:30:21

US3512272

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2013'	System	17 Sep 2020 17:30:21

US3512272

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2013'	System	17 Sep 2020 17:30:21

**US3512272**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2013'	System	17 Sep 2020 17:30:21

US3512272

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2013'	System	17 Sep 2020 17:30:21



US3512272

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Medical device implantation, LLT: Medical device implantation - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 11:01:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 11:01:13
Data point term sent to Coder	System	13 Nov 2020 12:59:32
User closed query 'For coding purposes, for term NECK DISC IMPLANT, please clarify. Is this a disc replacement of a medical device implant or other' (Site from System).	System	13 Nov 2020 12:59:30
Query 'For coding purposes, for term NECK DISC IMPLANT, please clarify. Is this a disc replacement of a medical device implant or other' answered with 'UPDATED' (Site from System).	Allison Crain (b) (4)	13 Nov 2020 12:59:30
Coding entries removed.	Allison Crain (b) (4)	13 Nov 2020 12:59:24
User entered 'NECK DISC MEDICAL DEVICE IMPLANT' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 12:59:24
User opened query 'For coding purposes, for term NECK DISC IMPLANT, please clarify. Is this a disc replacement of a medical device implant or other' (Site from System).	Coder Import (b) (4)	14 Oct 2020 19:55:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Medical device implantation, LLT: Medical device implantation - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 11:30:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 11:30:42
Data point term sent to Coder	System	17 Sep 2020 18:19:18
User entered 'NECK DISC IMPLANT'	Brenda Anderson (b) (4)	17 Sep 2020 18:18:59

**US3512272**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2013'	Brenda Anderson (b) (4)	17 Sep 2020 18:18:59

**US3512272**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:18:59

**US3512272**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:18:59

**US3512272**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2013'	Brenda Anderson (b) (4)	17 Sep 2020 18:18:59

**US3512272**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:18:59

**US3512272**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2013'	System	17 Sep 2020 18:18:59

**US3512272**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2013'	System	17 Sep 2020 18:18:59



**US3512272**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2013'	System	17 Sep 2020 18:18:59

**US3512272**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2013'	System	17 Sep 2020 18:18:59

US3512272

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Intervertebral disc injury, LLT: Intervertebral disc injury - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:47:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:47:43
Data point term sent to Coder	System	17 Sep 2020 18:19:19
User entered 'NECK 7TH DISC INJURY'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:17

US3512272

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2013'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:17

**US3512272**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:17

**US3512272**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:17

**US3512272**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2013'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:17

**US3512272**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:17



US3512272

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2013'	System	17 Sep 2020 18:19:17

**US3512272**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2013'	System	17 Sep 2020 18:19:17

**US3512272**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2013'	System	17 Sep 2020 18:19:17

**US3512272**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2013'	System	17 Sep 2020 18:19:17

US3512272

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:21:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:21:44
Data point term sent to Coder	System	17 Sep 2020 18:20:20
User entered 'TOTAL HYSTERECTOMY'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:34

US3512272

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2007'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:34

**US3512272**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:34

**US3512272**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:34



**US3512272**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2007'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:34

**US3512272**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:34

**US3512272**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2007'	System	17 Sep 2020 18:19:34

**US3512272**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2007'	System	17 Sep 2020 18:19:34

**US3512272**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2007'	System	17 Sep 2020 18:19:34

**US3512272**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2007'	System	17 Sep 2020 18:19:34

US3512272

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms benign (incl nipple), HLT: Breast and nipple neoplasms benign, PT: Benign breast neoplasm, LLT: Breast lump (benign) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 19:42:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 19:42:49
Data point term sent to Coder	System	17 Sep 2020 18:20:22
User entered 'BENIGN LUMP OF RIGHT BREAST'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:58

**US3512272**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1978'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:58



**US3512272**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:58

**US3512272**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:58

**US3512272**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:58:23**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1978'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:58

**US3512272**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:19:58

**US3512272**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1978'	System	17 Sep 2020 18:19:58

**US3512272**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1978'	System	17 Sep 2020 18:19:58

**US3512272**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1978'	System	17 Sep 2020 18:19:58

**US3512272**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1978'	System	17 Sep 2020 18:19:58



US3512272

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast neoplasm removal, PT: Benign breast lump removal, LLT: Benign breast lump removal - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:31:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:31:44
Data point term sent to Coder	System	17 Sep 2020 18:20:24
User entered 'REMOVAL OF BENIGN RIGHT BREAST LUMP'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:23

**US3512272**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1978'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:23

**US3512272**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:23

**US3512272**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:23

**US3512272**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:58:23**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1978'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:23

**US3512272**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:23

**US3512272**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1978'	System	17 Sep 2020 18:20:23

**US3512272**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1978'	System	17 Sep 2020 18:20:23



**US3512272**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1978'	System	17 Sep 2020 18:20:23

**US3512272**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1978'	System	17 Sep 2020 18:20:23

US3512272

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:22:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:22:43
Data point term sent to Coder	System	17 Sep 2020 18:21:25
User entered 'TUBAL LIGATION'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:43

**US3512272**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1981'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:43

**US3512272**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:43

**US3512272**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:43

**US3512272**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1981'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:43

**US3512272**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:20:43



**US3512272**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1981'	System	17 Sep 2020 18:20:43

**US3512272**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1981'	System	17 Sep 2020 18:20:43

**US3512272**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1981'	System	17 Sep 2020 18:20:43

**US3512272**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1981'	System	17 Sep 2020 18:20:43

US3512272

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Knee injury - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:22:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:22:44
Data point term sent to Coder	System	17 Sep 2020 18:21:25
User entered 'LEFT KNEE INJURY'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:14

**US3512272**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1993'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:14

**US3512272**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:14

**US3512272**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:14



**US3512272**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:58:23**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1993'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:14

**US3512272**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:14

**US3512272**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1993'	System	17 Sep 2020 18:21:14

**US3512272**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1993'	System	17 Sep 2020 18:21:14

**US3512272**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1993'	System	17 Sep 2020 18:21:14

**US3512272**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1993'	System	17 Sep 2020 18:21:14

US3512272

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:22:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:22:45
Data point term sent to Coder	System	17 Sep 2020 18:22:27
User entered 'LEFT KNEE RECONSTRUCTION'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:35

**US3512272**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1993'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:35



**US3512272**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:35

**US3512272**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:35

**US3512272**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 1993'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:35

**US3512272**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:21:35

**US3512272**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1993'	System	17 Sep 2020 18:21:35

**US3512272**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1993'	System	17 Sep 2020 18:21:35

US3512272

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 1993'	System	17 Sep 2020 18:21:35

**US3512272**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '1993'	System	17 Sep 2020 18:21:35



US3512272

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 15:20:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 15:20:19
Data point term sent to Coder	System	29 Jan 2021 15:19:24
User entered 'VITAMIN D DEFICIENCY'	Allison Crain (b) (4)	29 Jan 2021 15:19:01

**US3512272**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2016'	Allison Crain (b) (4)	29 Jan 2021 15:19:01

**US3512272**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Allison Crain (b) (4)	29 Jan 2021 15:19:01

**US3512272**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:58:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Jan 2021 15:19:01

**US3512272**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	29 Jan 2021 15:19:01

**US3512272**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:58:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Allison Crain (b) (4)	29 Jan 2021 15:19:01

**US3512272**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'Jan 2016'	System	29 Jan 2021 15:19:01

**US3512272**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '2016'	System	29 Jan 2021 15:19:01



**US3512272**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	29 Jan 2021 15:19:01

**US3512272**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	29 Jan 2021 15:19:01

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21

**US3512272**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '12:07'	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21

**US3512272**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '17 Sep 2020 12:07'	System	17 Sep 2020 18:22:21

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '66' in	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21
DataPoint set to visible.	System	17 Sep 2020 17:21:29

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '260' lb	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21
DataPoint set to visible.	System	17 Sep 2020 17:21:29



US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '42.05284'	System	17 Sep 2020 18:22:21
DataPoint set to visible.	System	17 Sep 2020 17:21:29

**US3512272**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'kg/m2'	System	17 Sep 2020 18:22:21
DataPoint set to visible.	System	17 Sep 2020 17:21:29

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21

**US3512272**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21

**US3512272**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'bpm'	System	17 Sep 2020 18:22:21

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21



US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'breaths/min'	System	17 Sep 2020 18:22:21

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21

**US3512272**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'mmHg'	System	17 Sep 2020 18:22:21

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	17 Sep 2020 18:22:21

**US3512272**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'mmHg'	System	17 Sep 2020 18:22:21

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53

US3512272

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53

US3512272

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:25:14



**US3512272**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:58:23**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	Brenda Anderson (b) (4)	17 Sep 2020 17:25:14

**US3512272**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:58:23**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	Brenda Anderson (b) (4)	17 Sep 2020 17:25:51

US3512272

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:23

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:25:51

US3512272

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:23

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Surgically sterile (SURGICALLY STERILE)'	Brenda Anderson (b) (4)	17 Sep 2020 17:25:51

US3512272

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:23

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:25:51

US3512272

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'UN UNK 2007'	Brenda Anderson (b) (4)	17 Sep 2020 17:25:51

**US3512272**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:58:23**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:25:51

US3512272

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:23

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:25:51



**US3512272**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:58:23**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 17:25:51

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

[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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

**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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

**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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

**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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

[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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

**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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57



US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

**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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

[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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

**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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

**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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57



US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

**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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

**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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'I'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'I'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'WORKS AT LEAST 5 DAYS/WEEK; INTERACTS W/>5 PEOPLE DAILY; HAS ATTENDED LARGE GROUP EVENTS IN THE PAST FEW WEEKS (CHURCH); PLANS ON ROUTINELY GOING TO PLACES WHERE PEOPLE GATHER'	Brenda Anderson (b) (4)	17 Sep 2020 18:24:57

US3512272

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:26:03

**US3512272**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	(b) (4) Brenda Anderson (b) (4)	17 Sep 2020 17:26:03



**US3512272**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	17 Sep 2020 17:26:03

**US3512272**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'VISIT1'	System	17 Sep 2020 17:26:03

US3512272

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:34:29

US3512272

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:23

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '145899'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:34:29

US3512272

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:23

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:34:29

US3512272

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:26:24

US3512272

Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:26:24

US3512272

Folder: Visit 1 Day 1

Form: Randomization

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Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:26:24



**US3512272**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:58:23**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:26:24

**US3512272**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:58:23**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:26:24

US3512272

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:23

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Allison Crain (b) (4)	15 Oct 2020 21:03:45
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:25:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:25:18

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '12:07'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '17 Sep 2020 12:07'	System	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '97.8' F	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

**US3512272**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:58:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '70'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'bpm'	System	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '18'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'breaths/min'	System	17 Sep 2020 18:17:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '126'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '80'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	17 Sep 2020 18:17:07



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered missing code ND - Not Done.	Brenda Anderson (b) (4)	17 Sep 2020 18:17:07

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '13:45'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '17 Sep 2020 13:45'	System	17 Sep 2020 18:17:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '97.5' F	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '69'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'bpm'	System	17 Sep 2020 18:17:39

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '18'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'breaths/min'	System	17 Sep 2020 18:17:39

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '149'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	17 Sep 2020 18:17:39

US3512272

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '95'	Brenda Anderson (b) (4)	17 Sep 2020 18:17:39



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	17 Sep 2020 18:17:39

US3512272

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 17:26:33

US3512272

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:26:33

US3512272

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 17:42:11

**US3512272**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:58:23**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:42:11

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 17:42:11

US3512272

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 17:42:11

US3512272

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	Brenda Anderson (b) (4)	17 Sep 2020 17:42:11



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Folder: Visit 1 Day 1

Form: Exposure

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[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '13:14'	Brenda Anderson (b) (4)	17 Sep 2020 17:42:11

US3512272

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '17 Sep 2020 13:14'	System	17 Sep 2020 17:42:11

US3512272

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Left Arm (LEFT ARM)'	Brenda Anderson (b) (4)	17 Sep 2020 17:42:11

US3512272

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'ONCE'	System	17 Sep 2020 17:42:11

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 17:42:11

US3512272

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:29:34

US3512272

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	Brenda Anderson (b) (4)	17 Sep 2020 18:29:34

US3512272

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '12:45'	Brenda Anderson (b) (4)	17 Sep 2020 18:29:34



**US3512272**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:58:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '17 Sep 2020 12:45'	System	17 Sep 2020 18:29:34

US3512272

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:58:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '17 Sep 2020'	(b) (4) Brenda Anderson (b) (4)	17 Sep 2020 18:29:49

US3512272

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Anderson (b) (4)	17 Sep 2020 18:29:49

US3512272

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:29:49

US3512272

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '12:28'	Brenda Anderson (b) (4)	17 Sep 2020 18:29:49

**US3512272**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '17 Sep 2020 12:28'	System	17 Sep 2020 18:29:49

US3512272

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Anderson (b) (4)	17 Sep 2020 18:29:49

US3512272

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:29:49



**US3512272**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:29:49

US3512272

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered empty.	System	17 Sep 2020 18:29:49

US3512272

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:29:58

**US3512272**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	17 Sep 2020 18:29:58

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:47:46', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1d1d6379-9ef9-4f95-a8b6-2245ef8d808b'	System	17 Sep 2020 17:49:16
User entered 'Yes (Y)'	System	17 Sep 2020 17:49:16

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:48:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1d1d6379-9ef9-4f95-a8b6-2245ef8d808b'	System	17 Sep 2020 17:49:16
User entered '97.5'	System	17 Sep 2020 17:49:16

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:48:53', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1d1d6379-9ef9-4f95-a8b6-2245ef8d808b'	System	17 Sep 2020 17:49:16
User entered 'No (N)'	System	17 Sep 2020 17:49:16



US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:49:06', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1d1d6379-9ef9-4f95-a8b6-2245ef8d808b'	System	17 Sep 2020 17:49:16
User entered '17 Sep 2020 13:49'	System	17 Sep 2020 17:49:16

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Sep 2020 13:34'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Sep 2020 16:04'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:56:07', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '840d33cb-6a5c-428e-a8b2-5c57036f6519'	System	17 Sep 2020 23:57:05
User entered 'Yes (Y)'	System	17 Sep 2020 23:57:05

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:56:32', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '840d33cb-6a5c-428e-a8b2-5c57036f6519'	System	17 Sep 2020 23:57:05
User entered '97.7'	System	17 Sep 2020 23:57:05

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:56:44', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '840d33cb-6a5c-428e-a8b2-5c57036f6519'	System	17 Sep 2020 23:57:05
User entered 'No (N)'	System	17 Sep 2020 23:57:05

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:57:01', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '840d33cb-6a5c-428e-a8b2-5c57036f6519'	System	17 Sep 2020 23:57:05
User entered '17 Sep 2020 19:57'	System	17 Sep 2020 23:57:05



US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Sep 2020 16:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 2'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:55:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '46756cb1-773a-4db5-9246-b72d87aacc22'	System	18 Sep 2020 22:55:36
User entered 'Yes (Y)'	System	18 Sep 2020 22:55:36

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:55:19', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '46756cb1-773a-4db5-9246-b72d87aacc22'	System	18 Sep 2020 22:55:36
User entered '98.4'	System	18 Sep 2020 22:55:36

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:55:26', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '46756cb1-773a-4db5-9246-b72d87aacc22'	System	18 Sep 2020 22:55:36
User entered 'No (N)'	System	18 Sep 2020 22:55:36

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:55:31', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '46756cb1-773a-4db5-9246-b72d87aacc22'	System	18 Sep 2020 22:55:36
User entered '18 Sep 2020 18:55'	System	18 Sep 2020 22:55:36

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:42:11



US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 3'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:09:16', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7ff05b9a-df96-467e-ba12-675681a06480'	System	19 Sep 2020 23:09:38
User entered 'Yes (Y)'	System	19 Sep 2020 23:09:38

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:09:23', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7ff05b9a-df96-467e-ba12-675681a06480'	System	19 Sep 2020 23:09:38
User entered '97.5'	System	19 Sep 2020 23:09:38

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:09:28', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7ff05b9a-df96-467e-ba12-675681a06480'	System	19 Sep 2020 23:09:38
User entered 'No (N)'	System	19 Sep 2020 23:09:38

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:09:33', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7ff05b9a-df96-467e-ba12-675681a06480'	System	19 Sep 2020 23:09:38
User entered '19 Sep 2020 19:09'	System	19 Sep 2020 23:09:38

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:42:11



US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 4'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:29:55', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '99ae7689-9098-44af-b39d-f4cda3ae384d'	System	20 Sep 2020 22:30:54
User entered 'Yes (Y)'	System	20 Sep 2020 22:30:54

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:30:01', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '99ae7689-9098-44af-b39d-f4cda3ae384d'	System	20 Sep 2020 22:30:54
User entered '96.5'	System	20 Sep 2020 22:30:54

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:30:24', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '99ae7689-9098-44af-b39d-f4cda3ae384d'	System	20 Sep 2020 22:30:54
User entered 'Yes (Y)'	System	20 Sep 2020 22:30:54

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted and documented' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 05:40:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Allison Crain (b) (4)	13 Nov 2020 12:58:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:30:42', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '99ae7689-9098-44af-b39d-f4cda3ae384d'	(b) (4)	
User entered '1'	System	20 Sep 2020 22:30:54
	System	20 Sep 2020 22:30:54
	System	20 Sep 2020 22:30:54

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:30:42', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '99ae7689-9098-44af-b39d-f4cda3ae384d'	System	20 Sep 2020 22:30:54
User entered '0'	System	20 Sep 2020 22:30:54

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:30:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '99ae7689-9098-44af-b39d-f4cda3ae384d'	System	20 Sep 2020 22:30:54
User entered '20 Sep 2020 18:30'	System	20 Sep 2020 22:30:54

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:42:11



US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 5'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:44:52', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b290c021-c29c-4f74-a2d8-43a8a9fe0f67'	System	21 Sep 2020 23:45:18
User entered 'Yes (Y)'	System	21 Sep 2020 23:45:18

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:45:01', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b290c021-c29c-4f74-a2d8-43a8a9fe0f67' User entered '97.0'	System	21 Sep 2020 23:45:18
	System	21 Sep 2020 23:45:18

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:45:06', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b290c021-c29c-4f74-a2d8-43a8a9fe0f67'	System	21 Sep 2020 23:45:18
User entered 'No (N)'	System	21 Sep 2020 23:45:18

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:45:12', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b290c021-c29c-4f74-a2d8-43a8a9fe0f67'	System	21 Sep 2020 23:45:18
User entered '21 Sep 2020 19:45'	System	21 Sep 2020 23:45:18

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:42:11



US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 6'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:08:20', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '59c9c551-c579-4d1d-83f8-373881ab6064'	System	23 Sep 2020 01:09:04
User entered 'Yes (Y)'	System	23 Sep 2020 01:09:04

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:08:29', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '59c9c551-c579-4d1d-83f8-373881ab6064' User entered '96.3'	System	23 Sep 2020 01:09:04
	System	23 Sep 2020 01:09:04

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:08:35', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '59c9c551-c579-4d1d-83f8-373881ab6064'	System	23 Sep 2020 01:09:04
User entered 'No (N)'	System	23 Sep 2020 01:09:04

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:08:56', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '59c9c551-c579-4d1d-83f8-373881ab6064'	System	23 Sep 2020 01:09:04
User entered '22 Sep 2020 21:08'	System	23 Sep 2020 01:09:04

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 7'	System	17 Sep 2020 17:42:11



US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:20:55', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f0fbe263-3c05-4bc1-83e9-36e60db1afd0'	System	24 Sep 2020 01:22:17
User entered 'Yes (Y)'	System	24 Sep 2020 01:22:17

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:21:39', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f0fbe263-3c05-4bc1-83e9-36e60db1afd0'	System	24 Sep 2020 01:22:17
User entered '96.8'	System	24 Sep 2020 01:22:17

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:21:54', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f0fbe263-3c05-4bc1-83e9-36e60db1afd0'	System	24 Sep 2020 01:22:17
User entered 'No (N)'	System	24 Sep 2020 01:22:17

US3512272

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:22:09', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f0fbe263-3c05-4bc1-83e9-36e60db1afd0'	System	24 Sep 2020 01:22:17
User entered '23 Sep 2020 21:22'	System	24 Sep 2020 01:22:17

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:49:36', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c50b7b80-0f90-408a-ac09-9e0594fa040b'	System	17 Sep 2020 17:50:23
User entered 'None (1)'	System	17 Sep 2020 17:50:23



US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:49:40', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c50b7b80-0f90-408a-ac09-9e0594fa040b'	System	17 Sep 2020 17:50:23
User entered 'No (N)'	System	17 Sep 2020 17:50:23

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:49:44', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c50b7b80-0f90-408a-ac09-9e0594fa040b'	System	17 Sep 2020 17:50:23
User entered 'No (N)'	System	17 Sep 2020 17:50:23

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:49:58', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c50b7b80-0f90-408a-ac09-9e0594fa040b'	System	17 Sep 2020 17:50:23
User entered 'None (1)'	System	17 Sep 2020 17:50:23

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:50:14', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c50b7b80-0f90-408a-ac09-9e0594fa040b'	System	17 Sep 2020 17:50:23
User entered '17 Sep 2020 13:50'	System	17 Sep 2020 17:50:23

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Sep 2020 13:34'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Sep 2020 16:04'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:57:22', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '4f2dbfea-a2b8-40bb-b04a-72a7b7e647f1'	System	17 Sep 2020 23:58:16
User entered 'None (1)'	System	17 Sep 2020 23:58:16



US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:57:27', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '4f2dbfea-a2b8-40bb-b04a-72a7b7e647f1'	System	17 Sep 2020 23:58:16
User entered 'No (N)'	System	17 Sep 2020 23:58:16

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:57:42', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '4f2dbfea-a2b8-40bb-b04a-72a7b7e647f1'	System	17 Sep 2020 23:58:16
User entered 'No (N)'	System	17 Sep 2020 23:58:16

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:58:03', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '4f2dbfea-a2b8-40bb-b04a-72a7b7e647f1'	System	17 Sep 2020 23:58:16
User entered 'None (1)'	System	17 Sep 2020 23:58:16

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:58:12', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '4f2dbfea-a2b8-40bb-b04a-72a7b7e647f1'	System	17 Sep 2020 23:58:16
User entered '17 Sep 2020 19:58'	System	17 Sep 2020 23:58:16

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Sep 2020 16:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 2'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:55:51', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f607b41a-9b33-4453-bb34-d651ec99e2b7'	System	18 Sep 2020 22:56:28
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 22:56:28



US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:55:56', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f607b41a-9b33-4453-bb34-d651ec99e2b7'	System	18 Sep 2020 22:56:28
User entered 'No (N)'	System	18 Sep 2020 22:56:28

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:56:09', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f607b41a-9b33-4453-bb34-d651ec99e2b7'	System	18 Sep 2020 22:56:28
User entered 'No (N)'	System	18 Sep 2020 22:56:28

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:56:18', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f607b41a-9b33-4453-bb34-d651ec99e2b7'	System	18 Sep 2020 22:56:28
User entered 'None (1)'	System	18 Sep 2020 22:56:28

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:56:23', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f607b41a-9b33-4453-bb34-d651ec99e2b7'	System	18 Sep 2020 22:56:28
User entered '18 Sep 2020 18:56'	System	18 Sep 2020 22:56:28

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 3'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:09:56', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ddda6d49-63fe-416f-baef-52515f4cc8d7'	System	19 Sep 2020 23:10:37
User entered 'None (1)'	System	19 Sep 2020 23:10:37



US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:10:01', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ddda6d49-63fe-416f-baef-52515f4cc8d7'	System	19 Sep 2020 23:10:37
User entered 'No (N)'	System	19 Sep 2020 23:10:37

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:10:06', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ddda6d49-63fe-416f-baef-52515f4cc8d7'	System	19 Sep 2020 23:10:37
User entered 'No (N)'	System	19 Sep 2020 23:10:37

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:10:23', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ddda6d49-63fe-416f-baef-52515f4cc8d7'	System	19 Sep 2020 23:10:37
User entered 'None (1)'	System	19 Sep 2020 23:10:37

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:10:29', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ddda6d49-63fe-416f-baef-52515f4cc8d7'	System	19 Sep 2020 23:10:37
User entered '19 Sep 2020 19:10'	System	19 Sep 2020 23:10:37

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 4'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:31:05', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1d085ed2-2395-46d5-9323-90fa303e574f'	System	20 Sep 2020 22:31:39
User entered 'None (1)'	System	20 Sep 2020 22:31:39



US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:31:10', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1d085ed2-2395-46d5-9323-90fa303e574f'	System	20 Sep 2020 22:31:39
User entered 'No (N)'	System	20 Sep 2020 22:31:39

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:31:14', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1d085ed2-2395-46d5-9323-90fa303e574f'	System	20 Sep 2020 22:31:39
User entered 'No (N)'	System	20 Sep 2020 22:31:39

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:31:27', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1d085ed2-2395-46d5-9323-90fa303e574f'	System	20 Sep 2020 22:31:39
User entered 'None (1)'	System	20 Sep 2020 22:31:39

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:31:35', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1d085ed2-2395-46d5-9323-90fa303e574f'	System	20 Sep 2020 22:31:39
User entered '20 Sep 2020 18:31'	System	20 Sep 2020 22:31:39

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 5'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:45:25', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1041b6f1-7754-4a9d-a890-701b80aa1ff8'	System	21 Sep 2020 23:45:52
User entered 'None (1)'	System	21 Sep 2020 23:45:52



US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:45:33', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1041b6f1-7754-4a9d-a890-701b80aa1ff8'	System	21 Sep 2020 23:45:52
User entered 'No (N)'	System	21 Sep 2020 23:45:52

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:45:37', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1041b6f1-7754-4a9d-a890-701b80aa1ff8'	System	21 Sep 2020 23:45:52
User entered 'No (N)'	System	21 Sep 2020 23:45:52

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:45:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1041b6f1-7754-4a9d-a890-701b80aa1ff8'	System	21 Sep 2020 23:45:52
User entered 'None (1)'	System	21 Sep 2020 23:45:52

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:45:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1041b6f1-7754-4a9d-a890-701b80aa1ff8'	System	21 Sep 2020 23:45:52
User entered '21 Sep 2020 19:45'	System	21 Sep 2020 23:45:52

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 6'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:07', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e5f51c94-27b2-4bb0-9455-805cd5cb2987'	System	23 Sep 2020 01:09:37
User entered 'None (1)'	System	23 Sep 2020 01:09:37



US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:12', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e5f51c94-27b2-4bb0-9455-805cd5cb2987'	System	23 Sep 2020 01:09:37
User entered 'No (N)'	System	23 Sep 2020 01:09:37

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:18', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e5f51c94-27b2-4bb0-9455-805cd5cb2987'	System	23 Sep 2020 01:09:37
User entered 'No (N)'	System	23 Sep 2020 01:09:37

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:22', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e5f51c94-27b2-4bb0-9455-805cd5cb2987'	System	23 Sep 2020 01:09:37
User entered 'None (1)'	System	23 Sep 2020 01:09:37

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:28', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e5f51c94-27b2-4bb0-9455-805cd5cb2987'	System	23 Sep 2020 01:09:37
User entered '22 Sep 2020 21:09'	System	23 Sep 2020 01:09:37

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 7'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:22:23', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6add8169-bb07-4009-ad5b-d386caca3788'	System	24 Sep 2020 01:23:10
User entered 'None (1)'	System	24 Sep 2020 01:23:10



US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:22:30', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6add8169-bb07-4009-ad5b-d386caca3788'	System	24 Sep 2020 01:23:10
User entered 'No (N)'	System	24 Sep 2020 01:23:10

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:22:35', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6add8169-bb07-4009-ad5b-d386caca3788'	System	24 Sep 2020 01:23:10
User entered 'No (N)'	System	24 Sep 2020 01:23:10

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:22:39', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6add8169-bb07-4009-ad5b-d386caca3788'	System	24 Sep 2020 01:23:10
User entered 'None (1)'	System	24 Sep 2020 01:23:10

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:23:00', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6add8169-bb07-4009-ad5b-d386caca3788'	System	24 Sep 2020 01:23:10
User entered '23 Sep 2020 21:23'	System	24 Sep 2020 01:23:10

US3512272

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:50:38', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c1de920e-bd33-4129-a1af-d2165fd1b742'	System	17 Sep 2020 17:51:43
User entered 'None (0)'	System	17 Sep 2020 17:51:43



US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:50:44', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c1de920e-bd33-4129-a1af-d2165fd1b742'	System	17 Sep 2020 17:51:43
User entered 'None (0)'	System	17 Sep 2020 17:51:43

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:50:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c1de920e-bd33-4129-a1af-d2165fd1b742'	System	17 Sep 2020 17:51:43
User entered 'None (0)'	System	17 Sep 2020 17:51:43

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:50:54', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c1de920e-bd33-4129-a1af-d2165fd1b742'	System	17 Sep 2020 17:51:43
User entered 'None (0)'	System	17 Sep 2020 17:51:43

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:50:58', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c1de920e-bd33-4129-a1af-d2165fd1b742'	System	17 Sep 2020 17:51:43
User entered 'None (0)'	System	17 Sep 2020 17:51:43

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:51:08', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c1de920e-bd33-4129-a1af-d2165fd1b742'	System	17 Sep 2020 17:51:43
User entered 'None (0)'	System	17 Sep 2020 17:51:43

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:51:21', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c1de920e-bd33-4129-a1af-d2165fd1b742'	System	17 Sep 2020 17:51:43
User entered 'No (N)'	System	17 Sep 2020 17:51:43

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T13:51:24', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c1de920e-bd33-4129-a1af-d2165fd1b742'	System	17 Sep 2020 17:51:43
User entered '17 Sep 2020 13:51'	System	17 Sep 2020 17:51:43

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Sep 2020 13:34'	System	17 Sep 2020 17:42:11



**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Sep 2020 16:04'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:58:29', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6e23294e-5b03-4015-9f86-89629b967e35'	System	17 Sep 2020 23:59:42
User entered 'None (0)'	System	17 Sep 2020 23:59:42

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:59:02', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6e23294e-5b03-4015-9f86-89629b967e35'	System	17 Sep 2020 23:59:42
User entered 'Some interference with activity (2)'	System	17 Sep 2020 23:59:42

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:59:07', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6e23294e-5b03-4015-9f86-89629b967e35'	System	17 Sep 2020 23:59:42
User entered 'None (0)'	System	17 Sep 2020 23:59:42

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:59:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6e23294e-5b03-4015-9f86-89629b967e35'	System	17 Sep 2020 23:59:42
User entered 'None (0)'	System	17 Sep 2020 23:59:42

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:59:17', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6e23294e-5b03-4015-9f86-89629b967e35'	System	17 Sep 2020 23:59:42
User entered 'None (0)'	System	17 Sep 2020 23:59:42

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:59:25', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6e23294e-5b03-4015-9f86-89629b967e35'	System	17 Sep 2020 23:59:42
User entered 'None (0)'	System	17 Sep 2020 23:59:42



US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:59:33', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6e23294e-5b03-4015-9f86-89629b967e35'	System	17 Sep 2020 23:59:42
User entered 'No (N)'	System	17 Sep 2020 23:59:42

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-17T19:59:39', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6e23294e-5b03-4015-9f86-89629b967e35'	System	17 Sep 2020 23:59:42
User entered '17 Sep 2020 19:59'	System	17 Sep 2020 23:59:42

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Sep 2020 16:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 2'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:56:46', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd0c7e0e4-5c3d-46a3-9013-132ad1506c9c'	System	18 Sep 2020 22:57:36
User entered 'No interference with activity (1)'	System	18 Sep 2020 22:57:36

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:56:57', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd0c7e0e4-5c3d-46a3-9013-132ad1506c9c'	System	18 Sep 2020 22:57:36
User entered 'None (0)'	System	18 Sep 2020 22:57:36

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:57:10', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd0c7e0e4-5c3d-46a3-9013-132ad1506c9c'	System	18 Sep 2020 22:57:36
User entered 'No interference with activity (1)'	System	18 Sep 2020 22:57:36



US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:57:14', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd0c7e0e4-5c3d-46a3-9013-132ad1506c9c'	System	18 Sep 2020 22:57:36
User entered 'None (0)'	System	18 Sep 2020 22:57:36

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:57:18', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd0c7e0e4-5c3d-46a3-9013-132ad1506c9c'	System	18 Sep 2020 22:57:36
User entered 'None (0)'	System	18 Sep 2020 22:57:36

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:57:22', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd0c7e0e4-5c3d-46a3-9013-132ad1506c9c'	System	18 Sep 2020 22:57:36
User entered 'None (0)'	System	18 Sep 2020 22:57:36

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:57:26', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd0c7e0e4-5c3d-46a3-9013-132ad1506c9c'	System	18 Sep 2020 22:57:36
User entered 'No (N)'	System	18 Sep 2020 22:57:36

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-18T18:57:30', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd0c7e0e4-5c3d-46a3-9013-132ad1506c9c'	System	18 Sep 2020 22:57:36
User entered '18 Sep 2020 18:57'	System	18 Sep 2020 22:57:36

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 3'	System	17 Sep 2020 17:42:11



US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:10:45', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8657a846-5dcd-4bc4-b942-e8d12fdf5520'	System	19 Sep 2020 23:11:28
User entered 'None (0)'	System	19 Sep 2020 23:11:28

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:10:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8657a846-5dcd-4bc4-b942-e8d12fdf5520'	System	19 Sep 2020 23:11:28
User entered 'None (0)'	System	19 Sep 2020 23:11:28

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:10:57', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8657a846-5dcd-4bc4-b942-e8d12fdf5520'	System	19 Sep 2020 23:11:28
User entered 'None (0)'	System	19 Sep 2020 23:11:28

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:11:02', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8657a846-5dcd-4bc4-b942-e8d12fdf5520'	System	19 Sep 2020 23:11:28
User entered 'None (0)'	System	19 Sep 2020 23:11:28

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:11:06', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8657a846-5dcd-4bc4-b942-e8d12fdf5520'	System	19 Sep 2020 23:11:28
User entered 'None (0)'	System	19 Sep 2020 23:11:28

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:11:10', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8657a846-5dcd-4bc4-b942-e8d12fdf5520'	System	19 Sep 2020 23:11:28
User entered 'None (0)'	System	19 Sep 2020 23:11:28

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:11:16', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8657a846-5dcd-4bc4-b942-e8d12fdf5520'	System	19 Sep 2020 23:11:28
User entered 'No (N)'	System	19 Sep 2020 23:11:28

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-19T19:11:22', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8657a846-5dcd-4bc4-b942-e8d12fdf5520'	System	19 Sep 2020 23:11:28
User entered '19 Sep 2020 19:11'	System	19 Sep 2020 23:11:28



**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 4'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:32:27', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a098621a-49ee-4317-a520-9def110fa4e1'	System	20 Sep 2020 22:33:21
User entered 'None (0)'	System	20 Sep 2020 22:33:21

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:32:31', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a098621a-49ee-4317-a520-9def110fa4e1'	System	20 Sep 2020 22:33:21
User entered 'None (0)'	System	20 Sep 2020 22:33:21

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:32:42', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a098621a-49ee-4317-a520-9def110fa4e1'	System	20 Sep 2020 22:33:21
User entered 'No interference with activity (1)'	System	20 Sep 2020 22:33:21

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:32:47', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a098621a-49ee-4317-a520-9def110fa4e1'	System	20 Sep 2020 22:33:21
User entered 'None (0)'	System	20 Sep 2020 22:33:21

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:32:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a098621a-49ee-4317-a520-9def110fa4e1'	System	20 Sep 2020 22:33:21
User entered 'None (0)'	System	20 Sep 2020 22:33:21



US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:33:01', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a098621a-49ee-4317-a520-9def110fa4e1'	System	20 Sep 2020 22:33:21
User entered 'None (0)'	System	20 Sep 2020 22:33:21

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:33:06', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a098621a-49ee-4317-a520-9def110fa4e1'	System	20 Sep 2020 22:33:21
User entered 'No (N)'	System	20 Sep 2020 22:33:21

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-20T18:33:15', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a098621a-49ee-4317-a520-9def110fa4e1'	System	20 Sep 2020 22:33:21
User entered '20 Sep 2020 18:33'	System	20 Sep 2020 22:33:21

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 5'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:46:00', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '948b10f4-6f1f-4d58-82f2-fbdf22904def' User entered 'None (0)'	System	21 Sep 2020 23:46:44
	System	21 Sep 2020 23:46:44

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:46:06', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '948b10f4-6f1f-4d58-82f2-fbdf22904def'	System	21 Sep 2020 23:46:44
User entered 'None (0)'	System	21 Sep 2020 23:46:44



US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:46:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '948b10f4-6f1f-4d58-82f2-fbdf22904def'	System	21 Sep 2020 23:46:44
User entered 'None (0)'	System	21 Sep 2020 23:46:44

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:46:22', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '948b10f4-6f1f-4d58-82f2-fbdf22904def'	System	21 Sep 2020 23:46:44
User entered 'None (0)'	System	21 Sep 2020 23:46:44

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:46:25', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '948b10f4-6f1f-4d58-82f2-fbdf22904def'	System	21 Sep 2020 23:46:44
User entered 'None (0)'	System	21 Sep 2020 23:46:44

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:46:28', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '948b10f4-6f1f-4d58-82f2-fbdf22904def' User entered 'None (0)'	System	21 Sep 2020 23:46:44
	System	21 Sep 2020 23:46:44

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:46:33', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '948b10f4-6f1f-4d58-82f2-fbdf22904def'	System	21 Sep 2020 23:46:44
User entered 'No (N)'	System	21 Sep 2020 23:46:44

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-21T19:46:38', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '948b10f4-6f1f-4d58-82f2-fbdf22904def'	System	21 Sep 2020 23:46:44
User entered '21 Sep 2020 19:46'	System	21 Sep 2020 23:46:44

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:42:11



**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 6'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:36', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '43595464-1ca0-46b2-b664-0fd89104c705'	System	23 Sep 2020 01:10:16
User entered 'None (0)'	System	23 Sep 2020 01:10:16

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:40', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '43595464-1ca0-46b2-b664-0fd89104c705'	System	23 Sep 2020 01:10:16
User entered 'None (0)'	System	23 Sep 2020 01:10:16

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '43595464-1ca0-46b2-b664-0fd89104c705'	System	23 Sep 2020 01:10:16
User entered 'None (0)'	System	23 Sep 2020 01:10:16

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:46', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '43595464-1ca0-46b2-b664-0fd89104c705'	System	23 Sep 2020 01:10:16
User entered 'None (0)'	System	23 Sep 2020 01:10:16

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '43595464-1ca0-46b2-b664-0fd89104c705'	System	23 Sep 2020 01:10:16
User entered 'None (0)'	System	23 Sep 2020 01:10:16

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:09:55', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '43595464-1ca0-46b2-b664-0fd89104c705'	System	23 Sep 2020 01:10:16
User entered 'None (0)'	System	23 Sep 2020 01:10:16

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:10:00', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '43595464-1ca0-46b2-b664-0fd89104c705'	System	23 Sep 2020 01:10:16
User entered 'No (N)'	System	23 Sep 2020 01:10:16



**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-22T21:10:06', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '43595464-1ca0-46b2-b664-0fd89104c705'	System	23 Sep 2020 01:10:16
User entered '22 Sep 2020 21:10'	System	23 Sep 2020 01:10:16

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 7'	System	17 Sep 2020 17:42:11

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:23:16', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '194ddb52-dab9-452b-a3d7-5524b2e32a47'	System	24 Sep 2020 01:24:47
User entered 'None (0)'	System	24 Sep 2020 01:24:47

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:23:29', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '194ddb52-dab9-452b-a3d7-5524b2e32a47'	System	24 Sep 2020 01:24:47
User entered 'None (0)'	System	24 Sep 2020 01:24:47

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:23:45', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '194ddb52-dab9-452b-a3d7-5524b2e32a47'	System	24 Sep 2020 01:24:47
User entered 'None (0)'	System	24 Sep 2020 01:24:47

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:24:18', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '194ddb52-dab9-452b-a3d7-5524b2e32a47'	System	24 Sep 2020 01:24:47
User entered 'No interference with activity (1)'	System	24 Sep 2020 01:24:47



US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:24:24', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '194ddb52-dab9-452b-a3d7-5524b2e32a47'	System	24 Sep 2020 01:24:47
User entered 'None (0)'	System	24 Sep 2020 01:24:47

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:24:28', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '194ddb52-dab9-452b-a3d7-5524b2e32a47'	System	24 Sep 2020 01:24:47
User entered 'None (0)'	System	24 Sep 2020 01:24:47

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:24:34', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '194ddb52-dab9-452b-a3d7-5524b2e32a47'	System	24 Sep 2020 01:24:47
User entered 'No (N)'	System	24 Sep 2020 01:24:47

US3512272

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-23T21:24:39', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '194ddb52-dab9-452b-a3d7-5524b2e32a47'	System	24 Sep 2020 01:24:47
User entered '23 Sep 2020 21:24'	System	24 Sep 2020 01:24:47

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	24 Sep 2020 01:24:47
User entered 'Day 8'	System	24 Sep 2020 01:24:47

US3512272

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 07:58:23

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-24T14:29:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '094a3ad0-10d6-46cc-af8c-3dfca0f01d26'	System	24 Sep 2020 18:30:11
User entered 'None (0)'	System	24 Sep 2020 18:30:11



**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-24T14:30:01', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '094a3ad0-10d6-46cc-af8c-3dfca0f01d26'	System	24 Sep 2020 18:30:11
User entered '24 Sep 2020 14:30'	System	24 Sep 2020 18:30:11

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 01:24:47

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 01:24:47

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	24 Sep 2020 01:24:47
User entered 'Day 8'	System	24 Sep 2020 01:24:47

US3512272

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-24T14:30:11', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8be4f6a3-a086-423a-ac6d-1ece79d0732e'	System	24 Sep 2020 18:30:24
User entered 'No (N)'	System	24 Sep 2020 18:30:24

US3512272

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-09-24T14:30:14', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '8be4f6a3-a086-423a-ac6d-1ece79d0732e'	System	24 Sep 2020 18:30:24
User entered '24 Sep 2020 14:30'	System	24 Sep 2020 18:30:24

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 01:24:47

**US3512272**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 01:24:47



**US3512272**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:19:58

**US3512272**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '24 Sep 2020'	Taylor Johnson (b) (4)	24 Sep 2020 23:19:58

**US3512272**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:19:58

US3512272

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:19:58

US3512272

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:20:02

**US3512272**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	24 Sep 2020 23:20:02

**US3512272**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	01 Oct 2020 18:44:51

**US3512272**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '01 Oct 2020'	(b) (4) Taylor Johnson (b) (4)	01 Oct 2020 18:44:51



**US3512272**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Johnson (b) (4)	01 Oct 2020 18:44:51

US3512272

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Taylor Johnson (b) (4)	01 Oct 2020 18:44:51

**US3512272**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	01 Oct 2020 18:44:57

**US3512272**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	01 Oct 2020 18:44:57

**US3512272**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	09 Oct 2020 17:23:12

**US3512272**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '9 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	09 Oct 2020 17:23:12

**US3512272**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	09 Oct 2020 17:23:12

US3512272

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Oct 2020 17:23:12



US3512272

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	09 Oct 2020 17:23:17

**US3512272**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	09 Oct 2020 17:23:17

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Allison Crain (b) (4)	15 Oct 2020 21:03:57

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15 Oct 2020'	Allison Crain (b) (4)	15 Oct 2020 21:03:57

US3512272

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	15 Oct 2020 21:03:57

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'VISIT2'	System	15 Oct 2020 21:03:57

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User accepted default value 'Pre-Dose (PREDOSE)'	Allison Crain (b) (4) (b) (4)	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:00



US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15 Oct 2020'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:00

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15:24'	Allison Crain (b) (4)	15 Oct 2020 21:21:00

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '15 Oct 2020 15:24'	System	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '97.8' F	Allison Crain (b) (4)	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:00

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '73'	Allison Crain (b) (4)	15 Oct 2020 21:21:00

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'bpm'	System	15 Oct 2020 21:21:00



US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '20'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'breaths/min'	System	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '136'	Allison Crain (b) (4)	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '84'	Allison Crain (b) (4)	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	15 Oct 2020 21:21:00

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User accepted default value 'Post-Dose (POSTDOSE)'	Allison Crain (b) (4) (b) (4)	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:33



US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15 Oct 2020'	Allison Crain (b) (4)	15 Oct 2020 21:21:33

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '16:58'	Allison Crain (b) (4)	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '15 Oct 2020 16:58'	System	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '97.9' F	Allison Crain (b) (4)	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '64'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'bpm'	System	15 Oct 2020 21:21:33



US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '18'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'breaths/min'	System	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '175'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '97'	Allison Crain (b) (4)	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	15 Oct 2020 21:21:33

US3512272

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:44

US3512272

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15 Oct 2020'	Allison Crain (b) (4)	15 Oct 2020 21:21:44



**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:58:23**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Allison Crain (b) (4)	15 Oct 2020 20:57:04

US3512272

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Allison Crain (b) (4)	15 Oct 2020 20:57:04

US3512272

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Allison Crain (b) (4)	15 Oct 2020 20:57:04

US3512272

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 20:57:04

US3512272

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15 Oct 2020'	Allison Crain (b) (4)	15 Oct 2020 20:57:04

US3512272

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '16:27'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 20:57:04

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:58:23**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '15 Oct 2020 16:27'	System	15 Oct 2020 20:57:04

US3512272

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Left Arm (LEFT ARM)'	Allison Crain (b) (4)	15 Oct 2020 20:57:04



US3512272

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'ONCE'	System	15 Oct 2020 20:57:04

US3512272

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 20:57:04

US3512272

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:57

US3512272

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15 Oct 2020'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:21:57

US3512272

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered '15:53' reason for change: Data Entry Error	System	15 Oct 2020 21:24:13
User opened query 'Data is required. Please provide.' (Site from System).	Allison Crain (b) (4)	15 Oct 2020 21:24:13
User entered empty.	(b) (4)	
	System	15 Oct 2020 21:21:57
	Allison Crain (b) (4)	15 Oct 2020 21:21:57
	(b) (4)	

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:58:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '15 Oct 2020 15:53'	System	15 Oct 2020 21:24:13
User entered empty.	System	15 Oct 2020 21:21:57

US3512272

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:58:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15 Oct 2020'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:22:08

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Allison Crain (b) (4) (b) (4)	15 Oct 2020 21:22:08



**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:22:08

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15:30'	Allison Crain (b) (4)	15 Oct 2020 21:22:08

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '15 Oct 2020 15:30'	System	15 Oct 2020 21:22:08

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Allison Crain (b) (4) (b) (4)	15 Oct 2020 21:22:08

US3512272

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:22:08

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:58:23**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Allison Crain (b) (4)	15 Oct 2020 21:22:08

**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered empty.	System	15 Oct 2020 21:22:08

US3512272

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	15 Oct 2020 21:22:13



**US3512272**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	15 Oct 2020 21:22:13

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:57:34', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '2f1707a8-7680-4652-8138-ff0fcc2021cb'	System	15 Oct 2020 20:58:08
User entered 'Yes (Y)'	System	15 Oct 2020 20:58:08

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:57:44', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '2f1707a8-7680-4652-8138-ff0fcc2021cb' User entered '97.9'	System	15 Oct 2020 20:58:08
	System	15 Oct 2020 20:58:08

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:57:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '2f1707a8-7680-4652-8138-ff0fcc2021cb'	System	15 Oct 2020 20:58:08
User entered 'No (N)'	System	15 Oct 2020 20:58:08

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:58:05', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '2f1707a8-7680-4652-8138-ff0fcc2021cb'	System	15 Oct 2020 20:58:08
User entered '15 Oct 2020 16:58'	System	15 Oct 2020 20:58:08

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '15 Oct 2020 16:47'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '15 Oct 2020 19:17'	System	15 Oct 2020 20:57:04



US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:00:47', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '50b1edb1-5593-4863-8e9a-b5f81b7f3b25'	System	16 Oct 2020 01:01:24
User entered 'Yes (Y)'	System	16 Oct 2020 01:01:24

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:00:58', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '50b1edb1-5593-4863-8e9a-b5f81b7f3b25'	System	16 Oct 2020 01:01:24
User entered '97.6'	System	16 Oct 2020 01:01:24

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:01:05', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '50b1edb1-5593-4863-8e9a-b5f81b7f3b25'	System	16 Oct 2020 01:01:24
User entered 'Yes (Y)'	System	16 Oct 2020 01:01:24

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted and discussed medication which was misreported by participant. She took her regular medication for chronic history of leg pain. Nothing to do with vaccine.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:05:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Sheldon Warren (b) (4)	23 Oct 2020 13:54:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:01:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '50b1edb1-5593-4863-8e9a-b5f81b7f3b25'	System	16 Oct 2020 01:01:24
User entered '1'	System	16 Oct 2020 01:01:24

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:01:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '50b1edb1-5593-4863-8e9a-b5f81b7f3b25'	System	16 Oct 2020 01:01:24
User entered '0'	System	16 Oct 2020 01:01:24

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:01:21', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '50b1edb1-5593-4863-8e9a-b5f81b7f3b25'	System	16 Oct 2020 01:01:24
User entered '15 Oct 2020 21:01'	System	16 Oct 2020 01:01:24

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '15 Oct 2020 20:12'	System	15 Oct 2020 20:57:04



US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 2'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:50:05', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '82986a17-a598-4c0e-8839-124ab5f4c43d'	System	17 Oct 2020 01:50:38
User entered 'Yes (Y)'	System	17 Oct 2020 01:50:38

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:50:11', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '82986a17-a598-4c0e-8839-124ab5f4c43d'	System	17 Oct 2020 01:50:38
User entered '97.8'	System	17 Oct 2020 01:50:38

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:50:21', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '82986a17-a598-4c0e-8839-124ab5f4c43d'	System	17 Oct 2020 01:50:38
User entered 'Yes (Y)'	System	17 Oct 2020 01:50:38

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted and discussed medication which was misreported by participant. She took her regular medication for chronic history of leg pain. Nothing to do with vaccine.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 05:05:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Sheldon Warren (b) (4)	23 Oct 2020 13:54:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:50:29', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '82986a17-a598-4c0e-8839-124ab5f4c43d'	System	17 Oct 2020 01:50:38
User entered '1'	System	17 Oct 2020 01:50:38

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:50:29', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '82986a17-a598-4c0e-8839-124ab5f4c43d' User entered '0'	System	17 Oct 2020 01:50:38
	System	17 Oct 2020 01:50:38

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:50:34', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '82986a17-a598-4c0e-8839-124ab5f4c43d'	System	17 Oct 2020 01:50:38
User entered '16 Oct 2020 21:50'	System	17 Oct 2020 01:50:38



US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 3'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:18:37', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a071cad3-c511-443d-8ed7-cbc3df6ed01b'	System	18 Oct 2020 00:20:05
User entered 'Yes (Y)'	System	18 Oct 2020 00:20:05

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:19:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a071cad3-c511-443d-8ed7-cbc3df6ed01b'	System	18 Oct 2020 00:20:05
User entered '98.6'	System	18 Oct 2020 00:20:05

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:19:54', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a071cad3-c511-443d-8ed7-cbc3df6ed01b'	System	18 Oct 2020 00:20:05
User entered 'No (N)'	System	18 Oct 2020 00:20:05

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:19:59', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a071cad3-c511-443d-8ed7-cbc3df6ed01b'	System	18 Oct 2020 00:20:05
User entered '17 Oct 2020 20:19'	System	18 Oct 2020 00:20:05

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 20:57:04



US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 4'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:29:59', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a300dbe6-4088-4df8-9437-afcabdf717a2'	System	18 Oct 2020 23:30:52
User entered 'Yes (Y)'	System	18 Oct 2020 23:30:52

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:30:31', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a300dbe6-4088-4df8-9437-afcabdf717a2'	System	18 Oct 2020 23:30:52
User entered '98.0'	System	18 Oct 2020 23:30:52

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:30:42', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a300dbe6-4088-4df8-9437-afcabdf717a2'	System	18 Oct 2020 23:30:52
User entered 'No (N)'	System	18 Oct 2020 23:30:52

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:30:47', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a300dbe6-4088-4df8-9437-afcabdf717a2'	System	18 Oct 2020 23:30:52
User entered '18 Oct 2020 19:30'	System	18 Oct 2020 23:30:52

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 20:57:04



US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 5'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:14:11', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '9ae6142d-3f1a-4ddc-bc1c-012fa0dbb28c'	System	20 Oct 2020 00:14:33
User entered 'Yes (Y)'	System	20 Oct 2020 00:14:33

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:14:17', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '9ae6142d-3f1a-4ddc-bc1c-012fa0dbb28c'	System	20 Oct 2020 00:14:33
User entered '96.8'	System	20 Oct 2020 00:14:33

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:14:22', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '9ae6142d-3f1a-4ddc-bc1c-012fa0dbb28c'	System	20 Oct 2020 00:14:33
User entered 'No (N)'	System	20 Oct 2020 00:14:33

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:14:26', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '9ae6142d-3f1a-4ddc-bc1c-012fa0dbb28c'	System	20 Oct 2020 00:14:33
User entered '19 Oct 2020 20:14'	System	20 Oct 2020 00:14:33

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 6'	System	15 Oct 2020 20:57:04



US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:04:20', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '9f38d060-37bd-4f12-b6ed-5ad6d52794aa'	System	21 Oct 2020 00:04:49
User entered 'Yes (Y)'	System	21 Oct 2020 00:04:49

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:04:28', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '9f38d060-37bd-4f12-b6ed-5ad6d52794aa'	System	21 Oct 2020 00:04:49
User entered '97.1'	System	21 Oct 2020 00:04:49

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:04:38', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '9f38d060-37bd-4f12-b6ed-5ad6d52794aa'	System	21 Oct 2020 00:04:49
User entered 'No (N)'	System	21 Oct 2020 00:04:49

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:04:42', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '9f38d060-37bd-4f12-b6ed-5ad6d52794aa'	System	21 Oct 2020 00:04:49
User entered '20 Oct 2020 20:04'	System	21 Oct 2020 00:04:49

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 7'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:37:22', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '436b690b-d9db-44cd-9834-886428e8c62d'	System	22 Oct 2020 03:37:52
User entered 'Yes (Y)'	System	22 Oct 2020 03:37:52



US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:37:33', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '436b690b-d9db-44cd-9834-886428e8c62d'	System	22 Oct 2020 03:37:52
User entered '97.8'	System	22 Oct 2020 03:37:52

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:37:39', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '436b690b-d9db-44cd-9834-886428e8c62d'	System	22 Oct 2020 03:37:52
User entered 'No (N)'	System	22 Oct 2020 03:37:52

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:37:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '436b690b-d9db-44cd-9834-886428e8c62d'	System	22 Oct 2020 03:37:52
User entered '21 Oct 2020 23:37'	System	22 Oct 2020 03:37:52

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:58:37', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a569db34-a598-4819-9d33-2c0bdf2aafa4'	System	15 Oct 2020 20:58:57
User entered 'None (1)'	System	15 Oct 2020 20:58:57

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:58:41', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a569db34-a598-4819-9d33-2c0bdf2aafa4'	System	15 Oct 2020 20:58:57
User entered 'No (N)'	System	15 Oct 2020 20:58:57



US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:58:45', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a569db34-a598-4819-9d33-2c0bdf2aafa4'	System	15 Oct 2020 20:58:57
User entered 'No (N)'	System	15 Oct 2020 20:58:57

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:58:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a569db34-a598-4819-9d33-2c0bdf2aafa4'	System	15 Oct 2020 20:58:57
User entered 'None (1)'	System	15 Oct 2020 20:58:57

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:58:54', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a569db34-a598-4819-9d33-2c0bdf2aafa4'	System	15 Oct 2020 20:58:57
User entered '15 Oct 2020 16:58'	System	15 Oct 2020 20:58:57

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '15 Oct 2020 16:47'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '15 Oct 2020 19:17'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:01:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5d644f5a-37a2-411f-94bf-f71a1939a186'	System	16 Oct 2020 01:02:42
User entered 'None (1)'	System	16 Oct 2020 01:02:42

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:02:09', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5d644f5a-37a2-411f-94bf-f71a1939a186'	System	16 Oct 2020 01:02:42
User entered 'No (N)'	System	16 Oct 2020 01:02:42



US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:02:14', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5d644f5a-37a2-411f-94bf-f71a1939a186'	System	16 Oct 2020 01:02:42
User entered 'No (N)'	System	16 Oct 2020 01:02:42

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:02:24', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5d644f5a-37a2-411f-94bf-f71a1939a186'	System	16 Oct 2020 01:02:42
User entered 'None (1)'	System	16 Oct 2020 01:02:42

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:02:38', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5d644f5a-37a2-411f-94bf-f71a1939a186'	System	16 Oct 2020 01:02:42
User entered '15 Oct 2020 21:02'	System	16 Oct 2020 01:02:42

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '15 Oct 2020 20:12'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 2'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:51:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c3710fe6-524b-40b8-988b-90b9234df348'	System	17 Oct 2020 01:52:34
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 01:52:34

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:52:01', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c3710fe6-524b-40b8-988b-90b9234df348'	System	17 Oct 2020 01:52:34
User entered 'No (N)'	System	17 Oct 2020 01:52:34



US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:52:15', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c3710fe6-524b-40b8-988b-90b9234df348'	System	17 Oct 2020 01:52:34
User entered 'No (N)'	System	17 Oct 2020 01:52:34

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:52:24', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c3710fe6-524b-40b8-988b-90b9234df348'	System	17 Oct 2020 01:52:34
User entered 'None (1)'	System	17 Oct 2020 01:52:34

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:52:29', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c3710fe6-524b-40b8-988b-90b9234df348'	System	17 Oct 2020 01:52:34
User entered '16 Oct 2020 21:52'	System	17 Oct 2020 01:52:34

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 3'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:20:09', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5efadf29-14da-4c2b-83f9-6ee401647c32'	System	18 Oct 2020 00:20:35
User entered 'None (1)'	System	18 Oct 2020 00:20:35

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:20:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5efadf29-14da-4c2b-83f9-6ee401647c32'	System	18 Oct 2020 00:20:35
User entered 'No (N)'	System	18 Oct 2020 00:20:35



US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:20:16', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5efadf29-14da-4c2b-83f9-6ee401647c32'	System	18 Oct 2020 00:20:35
User entered 'No (N)'	System	18 Oct 2020 00:20:35

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:20:22', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5efadf29-14da-4c2b-83f9-6ee401647c32'	System	18 Oct 2020 00:20:35
User entered 'None (1)'	System	18 Oct 2020 00:20:35

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:20:26', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '5efadf29-14da-4c2b-83f9-6ee401647c32'	System	18 Oct 2020 00:20:35
User entered '17 Oct 2020 20:20'	System	18 Oct 2020 00:20:35

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 4'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:30:59', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd575395f-25a6-4dfc-b323-c4f38be4c956'	System	18 Oct 2020 23:31:28
User entered 'None (1)'	System	18 Oct 2020 23:31:28

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:04', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd575395f-25a6-4dfc-b323-c4f38be4c956'	System	18 Oct 2020 23:31:28
User entered 'No (N)'	System	18 Oct 2020 23:31:28



US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:09', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd575395f-25a6-4dfc-b323-c4f38be4c956'	System	18 Oct 2020 23:31:28
User entered 'No (N)'	System	18 Oct 2020 23:31:28

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:18', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd575395f-25a6-4dfc-b323-c4f38be4c956'	System	18 Oct 2020 23:31:28
User entered 'None (1)'	System	18 Oct 2020 23:31:28

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:23', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd575395f-25a6-4dfc-b323-c4f38be4c956'	System	18 Oct 2020 23:31:28
User entered '18 Oct 2020 19:31'	System	18 Oct 2020 23:31:28

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 5'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:14:33', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '58e0e74d-5a9d-4fc1-a867-408488f2faa1'	System	20 Oct 2020 00:14:59
User entered 'None (1)'	System	20 Oct 2020 00:14:59

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:14:38', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '58e0e74d-5a9d-4fc1-a867-408488f2faa1'	System	20 Oct 2020 00:14:59
User entered 'No (N)'	System	20 Oct 2020 00:14:59



US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:14:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '58e0e74d-5a9d-4fc1-a867-408488f2faa1'	System	20 Oct 2020 00:14:59
User entered 'No (N)'	System	20 Oct 2020 00:14:59

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:14:49', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '58e0e74d-5a9d-4fc1-a867-408488f2faa1'	System	20 Oct 2020 00:14:59
User entered 'None (1)'	System	20 Oct 2020 00:14:59

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:14:53', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '58e0e74d-5a9d-4fc1-a867-408488f2faa1'	System	20 Oct 2020 00:14:59
User entered '19 Oct 2020 20:14'	System	20 Oct 2020 00:14:59

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 6'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:04:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ff32f35d-3b32-423b-ad5a-7dbfff691e7d'	System	21 Oct 2020 00:05:39
User entered 'None (1)'	System	21 Oct 2020 00:05:39

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:04:53', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ff32f35d-3b32-423b-ad5a-7dbfff691e7d'	System	21 Oct 2020 00:05:39
User entered 'No (N)'	System	21 Oct 2020 00:05:39



US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:04:57', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ff32f35d-3b32-423b-ad5a-7dbfff691e7d'	System	21 Oct 2020 00:05:39
User entered 'No (N)'	System	21 Oct 2020 00:05:39

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:05:21', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ff32f35d-3b32-423b-ad5a-7dbfff691e7d'	System	21 Oct 2020 00:05:39
User entered 'None (1)'	System	21 Oct 2020 00:05:39

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:05:30', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ff32f35d-3b32-423b-ad5a-7dbfff691e7d'	System	21 Oct 2020 00:05:39
User entered '20 Oct 2020 20:05'	System	21 Oct 2020 00:05:39

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 7'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:37:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '010dec86-339d-4cbc-8ea4-f43dabb4484f'	System	22 Oct 2020 03:38:20
User entered 'None (1)'	System	22 Oct 2020 03:38:20

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:37:55', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '010dec86-339d-4cbc-8ea4-f43dabb4484f'	System	22 Oct 2020 03:38:20
User entered 'No (N)'	System	22 Oct 2020 03:38:20



US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:37:59', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '010dec86-339d-4cbc-8ea4-f43dabb4484f'	System	22 Oct 2020 03:38:20
User entered 'No (N)'	System	22 Oct 2020 03:38:20

US3512272

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:38:08', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '010dec86-339d-4cbc-8ea4-f43dabb4484f'	System	22 Oct 2020 03:38:20
User entered 'None (1)'	System	22 Oct 2020 03:38:20

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:38:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '010dec86-339d-4cbc-8ea4-f43dabb4484f'	System	22 Oct 2020 03:38:20
User entered '21 Oct 2020 23:38'	System	22 Oct 2020 03:38:20

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:59:17', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bc7b73d9-99c4-4a41-9e0b-74189244e0ed'	System	15 Oct 2020 20:59:52
User entered 'None (0)'	System	15 Oct 2020 20:59:52

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:59:25', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bc7b73d9-99c4-4a41-9e0b-74189244e0ed'	System	15 Oct 2020 20:59:52
User entered 'None (0)'	System	15 Oct 2020 20:59:52



US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:59:29', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bc7b73d9-99c4-4a41-9e0b-74189244e0ed'	System	15 Oct 2020 20:59:52
User entered 'None (0)'	System	15 Oct 2020 20:59:52

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:59:31', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bc7b73d9-99c4-4a41-9e0b-74189244e0ed'	System	15 Oct 2020 20:59:52
User entered 'None (0)'	System	15 Oct 2020 20:59:52

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:59:36', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bc7b73d9-99c4-4a41-9e0b-74189244e0ed'	System	15 Oct 2020 20:59:52
User entered 'None (0)'	System	15 Oct 2020 20:59:52

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:59:38', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bc7b73d9-99c4-4a41-9e0b-74189244e0ed'	System	15 Oct 2020 20:59:52
User entered 'None (0)'	System	15 Oct 2020 20:59:52

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:59:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bc7b73d9-99c4-4a41-9e0b-74189244e0ed'	System	15 Oct 2020 20:59:52
User entered 'No (N)'	System	15 Oct 2020 20:59:52

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T16:59:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bc7b73d9-99c4-4a41-9e0b-74189244e0ed'	System	15 Oct 2020 20:59:52
User entered '15 Oct 2020 16:59'	System	15 Oct 2020 20:59:52

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '15 Oct 2020 16:47'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '15 Oct 2020 19:17'	System	15 Oct 2020 20:57:04



US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:02:54', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e3d66634-0172-497e-b914-1316c23c8602'	System	16 Oct 2020 01:03:41
User entered 'None (0)'	System	16 Oct 2020 01:03:41

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:03:02', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e3d66634-0172-497e-b914-1316c23c8602'	System	16 Oct 2020 01:03:41
User entered 'None (0)'	System	16 Oct 2020 01:03:41

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:03:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e3d66634-0172-497e-b914-1316c23c8602'	System	16 Oct 2020 01:03:41
User entered 'None (0)'	System	16 Oct 2020 01:03:41

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:03:19', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e3d66634-0172-497e-b914-1316c23c8602'	System	16 Oct 2020 01:03:41
User entered 'None (0)'	System	16 Oct 2020 01:03:41

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:03:23', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e3d66634-0172-497e-b914-1316c23c8602'	System	16 Oct 2020 01:03:41
User entered 'None (0)'	System	16 Oct 2020 01:03:41

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:03:26', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e3d66634-0172-497e-b914-1316c23c8602'	System	16 Oct 2020 01:03:41
User entered 'None (0)'	System	16 Oct 2020 01:03:41

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:03:32', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e3d66634-0172-497e-b914-1316c23c8602'	System	16 Oct 2020 01:03:41
User entered 'No (N)'	System	16 Oct 2020 01:03:41



US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-15T21:03:35', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'e3d66634-0172-497e-b914-1316c23c8602'	System	16 Oct 2020 01:03:41
User entered '15 Oct 2020 21:03'	System	16 Oct 2020 01:03:41

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '15 Oct 2020 20:12'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 2'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:53:45', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c68155db-2511-44d3-9156-a0c34e52dde6'	System	17 Oct 2020 01:55:31
User entered 'None (0)'	System	17 Oct 2020 01:55:31

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:54:10', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c68155db-2511-44d3-9156-a0c34e52dde6'	System	17 Oct 2020 01:55:31
User entered 'No interference with activity (1)'	System	17 Oct 2020 01:55:31

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:54:39', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c68155db-2511-44d3-9156-a0c34e52dde6'	System	17 Oct 2020 01:55:31
User entered 'None (0)'	System	17 Oct 2020 01:55:31

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:54:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c68155db-2511-44d3-9156-a0c34e52dde6'	System	17 Oct 2020 01:55:31
User entered 'None (0)'	System	17 Oct 2020 01:55:31



US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:54:52', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c68155db-2511-44d3-9156-a0c34e52dde6'	System	17 Oct 2020 01:55:31
User entered 'None (0)'	System	17 Oct 2020 01:55:31

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:58:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:54:55', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c68155db-2511-44d3-9156-a0c34e52dde6'	System	17 Oct 2020 01:55:31
User entered 'None (0)'	System	17 Oct 2020 01:55:31

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:55:20', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c68155db-2511-44d3-9156-a0c34e52dde6'	System	17 Oct 2020 01:55:31
User entered 'No (N)'	System	17 Oct 2020 01:55:31

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-16T21:55:26', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'c68155db-2511-44d3-9156-a0c34e52dde6'	System	17 Oct 2020 01:55:31
User entered '16 Oct 2020 21:55'	System	17 Oct 2020 01:55:31

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 3'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:20:32', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a075bc7f-c128-45d6-a6f0-122755dfe79c'	System	18 Oct 2020 00:21:23
User entered 'None (0)'	System	18 Oct 2020 00:21:23



**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:20:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a075bc7f-c128-45d6-a6f0-122755dfe79c'	System	18 Oct 2020 00:21:23
User entered 'No interference with activity (1)'	System	18 Oct 2020 00:21:23

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:20:54', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a075bc7f-c128-45d6-a6f0-122755dfe79c'	System	18 Oct 2020 00:21:23
User entered 'No interference with activity (1)'	System	18 Oct 2020 00:21:23

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:21:05', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a075bc7f-c128-45d6-a6f0-122755dfe79c'	System	18 Oct 2020 00:21:23
User entered 'None (0)'	System	18 Oct 2020 00:21:23

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:21:08', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a075bc7f-c128-45d6-a6f0-122755dfe79c'	System	18 Oct 2020 00:21:23
User entered 'None (0)'	System	18 Oct 2020 00:21:23

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:21:11', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a075bc7f-c128-45d6-a6f0-122755dfe79c'	System	18 Oct 2020 00:21:23
User entered 'None (0)'	System	18 Oct 2020 00:21:23

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:21:15', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a075bc7f-c128-45d6-a6f0-122755dfe79c'	System	18 Oct 2020 00:21:23
User entered 'No (N)'	System	18 Oct 2020 00:21:23

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-17T20:21:18', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'a075bc7f-c128-45d6-a6f0-122755dfe79c'	System	18 Oct 2020 00:21:23
User entered '17 Oct 2020 20:21'	System	18 Oct 2020 00:21:23

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 20:57:04



**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 4'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:32', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '73fdb4d5-1f10-4bdf-a82a-f4ab5c51c679'	System	18 Oct 2020 23:32:19
User entered 'None (0)'	System	18 Oct 2020 23:32:19

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:47', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '73fdb4d5-1f10-4bdf-a82a-f4ab5c51c679'	System	18 Oct 2020 23:32:19
User entered 'None (0)'	System	18 Oct 2020 23:32:19

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '73fdb4d5-1f10-4bdf-a82a-f4ab5c51c679'	System	18 Oct 2020 23:32:19
User entered 'None (0)'	System	18 Oct 2020 23:32:19

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:52', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '73fdb4d5-1f10-4bdf-a82a-f4ab5c51c679'	System	18 Oct 2020 23:32:19
User entered 'None (0)'	System	18 Oct 2020 23:32:19

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:55', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '73fdb4d5-1f10-4bdf-a82a-f4ab5c51c679'	System	18 Oct 2020 23:32:19
User entered 'None (0)'	System	18 Oct 2020 23:32:19

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:31:57', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '73fdb4d5-1f10-4bdf-a82a-f4ab5c51c679'	System	18 Oct 2020 23:32:19
User entered 'None (0)'	System	18 Oct 2020 23:32:19



US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:32:03', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '73fdb4d5-1f10-4bdf-a82a-f4ab5c51c679'	System	18 Oct 2020 23:32:19
User entered 'No (N)'	System	18 Oct 2020 23:32:19

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-18T19:32:15', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '73fdb4d5-1f10-4bdf-a82a-f4ab5c51c679'	System	18 Oct 2020 23:32:19
User entered '18 Oct 2020 19:32'	System	18 Oct 2020 23:32:19

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 5'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:15:00', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b5fbf244-4aa7-4bb4-8e2b-0a40a21e6d32'	System	20 Oct 2020 00:15:54
User entered 'None (0)'	System	20 Oct 2020 00:15:54

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:15:17', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b5fbf244-4aa7-4bb4-8e2b-0a40a21e6d32'	System	20 Oct 2020 00:15:54
User entered 'No interference with activity (1)'	System	20 Oct 2020 00:15:54

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:15:23', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b5fbf244-4aa7-4bb4-8e2b-0a40a21e6d32'	System	20 Oct 2020 00:15:54
User entered 'None (0)'	System	20 Oct 2020 00:15:54



US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:15:27', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b5fbf244-4aa7-4bb4-8e2b-0a40a21e6d32'	System	20 Oct 2020 00:15:54
User entered 'None (0)'	System	20 Oct 2020 00:15:54

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:15:34', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b5fbf244-4aa7-4bb4-8e2b-0a40a21e6d32'	System	20 Oct 2020 00:15:54
User entered 'None (0)'	System	20 Oct 2020 00:15:54

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:15:38', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b5fbf244-4aa7-4bb4-8e2b-0a40a21e6d32'	System	20 Oct 2020 00:15:54
User entered 'None (0)'	System	20 Oct 2020 00:15:54

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:15:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b5fbf244-4aa7-4bb4-8e2b-0a40a21e6d32'	System	20 Oct 2020 00:15:54
User entered 'No (N)'	System	20 Oct 2020 00:15:54

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-19T20:15:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'b5fbf244-4aa7-4bb4-8e2b-0a40a21e6d32'	System	20 Oct 2020 00:15:54
User entered '19 Oct 2020 20:15'	System	20 Oct 2020 00:15:54

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 6'	System	15 Oct 2020 20:57:04



US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:05:41', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7f69f116-b4c5-4456-9f83-d584b96a0fa0'	System	21 Oct 2020 00:06:34
User entered 'None (0)'	System	21 Oct 2020 00:06:34

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:05:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7f69f116-b4c5-4456-9f83-d584b96a0fa0'	System	21 Oct 2020 00:06:34
User entered 'None (0)'	System	21 Oct 2020 00:06:34

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:05:53', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7f69f116-b4c5-4456-9f83-d584b96a0fa0'	System	21 Oct 2020 00:06:34
User entered 'None (0)'	System	21 Oct 2020 00:06:34

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:06:02', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7f69f116-b4c5-4456-9f83-d584b96a0fa0'	System	21 Oct 2020 00:06:34
User entered 'None (0)'	System	21 Oct 2020 00:06:34

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:06:06', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7f69f116-b4c5-4456-9f83-d584b96a0fa0'	System	21 Oct 2020 00:06:34
User entered 'None (0)'	System	21 Oct 2020 00:06:34

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:06:18', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7f69f116-b4c5-4456-9f83-d584b96a0fa0'	System	21 Oct 2020 00:06:34
User entered 'None (0)'	System	21 Oct 2020 00:06:34

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:06:22', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7f69f116-b4c5-4456-9f83-d584b96a0fa0'	System	21 Oct 2020 00:06:34
User entered 'No (N)'	System	21 Oct 2020 00:06:34

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-20T20:06:27', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '7f69f116-b4c5-4456-9f83-d584b96a0fa0'	System	21 Oct 2020 00:06:34
User entered '20 Oct 2020 20:06'	System	21 Oct 2020 00:06:34



**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	15 Oct 2020 20:57:04
User entered 'Day 7'	System	15 Oct 2020 20:57:04

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:38:19', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bf9793e8-b110-4e25-bc9c-ff4360166cef'	System	22 Oct 2020 03:39:26
User entered 'None (0)'	System	22 Oct 2020 03:39:26

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:38:24', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bf9793e8-b110-4e25-bc9c-ff4360166cef'	System	22 Oct 2020 03:39:26
User entered 'None (0)'	System	22 Oct 2020 03:39:26

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:38:36', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bf9793e8-b110-4e25-bc9c-ff4360166cef'	System	22 Oct 2020 03:39:26
User entered 'None (0)'	System	22 Oct 2020 03:39:26

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:38:42', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bf9793e8-b110-4e25-bc9c-ff4360166cef'	System	22 Oct 2020 03:39:26
User entered 'None (0)'	System	22 Oct 2020 03:39:26

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:38:52', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bf9793e8-b110-4e25-bc9c-ff4360166cef'	System	22 Oct 2020 03:39:26
User entered 'None (0)'	System	22 Oct 2020 03:39:26



US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:38:58', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bf9793e8-b110-4e25-bc9c-ff4360166cef'	System	22 Oct 2020 03:39:26
User entered 'None (0)'	System	22 Oct 2020 03:39:26

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:39:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bf9793e8-b110-4e25-bc9c-ff4360166cef'	System	22 Oct 2020 03:39:26
User entered 'No (N)'	System	22 Oct 2020 03:39:26

US3512272

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-10-21T23:39:18', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bf9793e8-b110-4e25-bc9c-ff4360166cef'	System	22 Oct 2020 03:39:26
User entered '21 Oct 2020 23:39'	System	22 Oct 2020 03:39:26

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:58:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 20:57:04

**US3512272**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	23 Oct 2020 13:52:38

**US3512272**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '23 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	23 Oct 2020 13:52:38

US3512272

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	23 Oct 2020 13:52:38



US3512272

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Sheldon Warren (b) (4)	23 Oct 2020 13:52:38

US3512272

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	23 Oct 2020 13:52:43

**US3512272**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	23 Oct 2020 13:52:43

**US3512272**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	29 Oct 2020 22:20:59

**US3512272**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '29 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	29 Oct 2020 22:20:59

**US3512272**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	29 Oct 2020 22:20:59

US3512272

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Sheldon Warren (b) (4)	29 Oct 2020 22:20:59

**US3512272**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	29 Oct 2020 22:21:04



**US3512272**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	29 Oct 2020 22:21:04

**US3512272**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	05 Nov 2020 15:59:39

**US3512272**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '5 Nov 2020'	(b) (4) Sheldon Warren (b) (4)	05 Nov 2020 15:59:39

**US3512272**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	05 Nov 2020 15:59:39

US3512272

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Sheldon Warren (b) (4)	05 Nov 2020 15:59:39

US3512272

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	07 Nov 2020 19:53:55

**US3512272**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	07 Nov 2020 19:53:55

**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 12:53:50



**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '12 Nov 2020'	Allison Crain (b) (4)	13 Nov 2020 12:53:50

US3512272

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	13 Nov 2020 12:53:50

**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'VISIT3'	System	13 Nov 2020 12:53:50

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 12:54:20

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '12 Nov 2020'	Allison Crain (b) (4)	13 Nov 2020 12:54:20

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '13:30'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 12:54:20

**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '12 Nov 2020 13:30'	System	13 Nov 2020 12:54:20

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '98.1' F	Allison Crain (b) (4)	13 Nov 2020 12:54:20



US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 12:54:20

**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Allison Crain (b) (4)	13 Nov 2020 12:54:20

**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '78'	Allison Crain (b) (4)	13 Nov 2020 12:54:20

**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'bpm'	System	13 Nov 2020 12:54:20

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '18'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 12:54:20

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'breaths/min'	System	13 Nov 2020 12:54:20

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '115'	Allison Crain (b) (4)	13 Nov 2020 12:54:20

**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	13 Nov 2020 12:54:20



US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '75'	Allison Crain (b) (4)	13 Nov 2020 12:54:20

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'mmHg'	System	13 Nov 2020 12:54:20

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50

US3512272

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50

US3512272

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 12:55:13

US3512272

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Allison Crain (b) (4)	13 Nov 2020 12:55:13

US3512272

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 12:55:26

US3512272

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User closed query 'Per GCL Lab Reconciliation: Immuno: Sample dated 12NOV2020 is recorded under Visit 3 Day 57 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:04:51
Query 'Per GCL Lab Reconciliation: Immuno: Sample dated 12NOV2020 is recorded under Visit 3 Day 57 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'faxed PPD a DCF form to change unscheduled visit to V3' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	27 Nov 2020 14:48:47
User opened query 'Per GCL Lab Reconciliation: Immuno: Sample dated 12NOV2020 is recorded under Visit 3 Day 57 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:05:27
User entered '12 Nov 2020'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 12:55:26



**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:58:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15:42'	Allison Crain (b) (4)	13 Nov 2020 12:55:26

US3512272

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered '12 Nov 2020 15:42'	System	13 Nov 2020 12:55:26

US3512272

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 12:55:31

**US3512272**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	13 Nov 2020 12:55:31

**US3512272**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered 'Day 64'	System	17 Sep 2020 17:42:11

US3512272

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

[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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-11-19T04:46:27', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ff33bc84-74af-47ce-b1bb-32c1e10a7dc1'	System	19 Nov 2020 09:46:47
User entered 'No (N)'	System	19 Nov 2020 09:46:47

US3512272

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:23

Have you been exposed to someone with 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)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-11-19T04:46:35', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ff33bc84-74af-47ce-b1bb-32c1e10a7dc1'	System	19 Nov 2020 09:46:47
User entered 'No (N)'	System	19 Nov 2020 09:46:47

**US3512272**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-11-19T04:46:42', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ff33bc84-74af-47ce-b1bb-32c1e10a7dc1'	System	19 Nov 2020 09:46:47
User entered '19 Nov 2020 04:46:42'	System	19 Nov 2020 09:46:47



**US3512272**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:53:42
Data entry locked.	System	17 Sep 2020 17:42:11
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 17:42:11

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2020-11-25T16:28:33', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '97931fd3-89e5-48d8-aeef-693f6fb72ff2'	System	25 Nov 2020 21:29:18
User entered 'Yes (Y)'	System	25 Nov 2020 21:29:18

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2020-11-25T16:28:43', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '97931fd3-89e5-48d8-aeef-693f6fb72ff2'	System	25 Nov 2020 21:29:18
User entered 'No (N)'	System	25 Nov 2020 21:29:18

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-11-25T16:28:51', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '97931fd3-89e5-48d8-aeef-693f6fb72ff2'	System	25 Nov 2020 21:29:18
User entered 'No (N)'	System	25 Nov 2020 21:29:18

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-11-25T16:29:02', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '97931fd3-89e5-48d8-aeef-693f6fb72ff2'	System	25 Nov 2020 21:29:18
User entered 'No (N)'	System	25 Nov 2020 21:29:18

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-11-25T16:29:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '97931fd3-89e5-48d8-aeef-693f6fb72ff2'	System	25 Nov 2020 21:29:18
User entered '25 Nov 2020 16:29:13'	System	25 Nov 2020 21:29:18



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2020-12-02T14:24:56', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ebdace3e-f181-4ff5-b161-b233f5663b0c'	System	02 Dec 2020 19:25:14
User entered 'No (N)'	System	02 Dec 2020 19:25:14

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2020-12-02T14:25:01', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ebdace3e-f181-4ff5-b161-b233f5663b0c'	System	02 Dec 2020 19:25:14
User entered 'No (N)'	System	02 Dec 2020 19:25:14

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-12-02T14:25:09', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ebdace3e-f181-4ff5-b161-b233f5663b0c'	System	02 Dec 2020 19:25:14
User entered '02 Dec 2020 14:25:09'	System	02 Dec 2020 19:25:14

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2020-12-09T21:59:18', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ce348913-f660-46a4-a64a-e8aad21edb67'	System	10 Dec 2020 03:00:13
User entered 'Yes (Y)'	System	10 Dec 2020 03:00:13

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2020-12-09T21:59:23', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ce348913-f660-46a4-a64a-e8aad21edb67'	System	10 Dec 2020 03:00:13
User entered 'No (N)'	System	10 Dec 2020 03:00:13

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-12-09T21:59:28', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ce348913-f660-46a4-a64a-e8aad21edb67'	System	10 Dec 2020 03:00:13
User entered 'No (N)'	System	10 Dec 2020 03:00:13

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-12-09T21:59:36', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ce348913-f660-46a4-a64a-e8aad21edb67'	System	10 Dec 2020 03:00:13
User entered 'Yes (Y)'	System	10 Dec 2020 03:00:13

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-12-09T21:59:56', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ce348913-f660-46a4-a64a-e8aad21edb67'	System	10 Dec 2020 03:00:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Dec 2020 03:00:13

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-12-09T22:00:02', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'ce348913-f660-46a4-a64a-e8aad21edb67'	System	10 Dec 2020 03:00:13
User entered '09 Dec 2020 22:00:02'	System	10 Dec 2020 03:00:13

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2020-12-23T15:59:38', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6bec0daa-c2ec-4367-890f-8e102f9e41d7'	System	23 Dec 2020 20:59:58
User entered 'No (N)'	System	23 Dec 2020 20:59:58

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2020-12-23T15:59:45', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6bec0daa-c2ec-4367-890f-8e102f9e41d7'	System	23 Dec 2020 20:59:58
User entered 'No (N)'	System	23 Dec 2020 20:59:58

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-12-23T15:59:52', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6bec0daa-c2ec-4367-890f-8e102f9e41d7'	System	23 Dec 2020 20:59:58
User entered '23 Dec 2020 15:59:52'	System	23 Dec 2020 20:59:58



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2020-12-30T18:10:39', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '3200e547-115f-46d0-ab1f-67ca61c1d3e1'	System	30 Dec 2020 23:10:59
User entered 'No (N)'	System	30 Dec 2020 23:10:59

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2020-12-30T18:10:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '3200e547-115f-46d0-ab1f-67ca61c1d3e1'	System	30 Dec 2020 23:10:59
User entered 'No (N)'	System	30 Dec 2020 23:10:59

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2020-12-30T18:10:55', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '3200e547-115f-46d0-ab1f-67ca61c1d3e1' User entered '30 Dec 2020 18:10:55'	System	30 Dec 2020 23:10:59
	System	30 Dec 2020 23:10:59

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-01-16T22:21:10', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '90261dbc-d861-4c6f-bb66-f268c61aa518'	System	17 Jan 2021 03:21:33
User entered 'No (N)'	System	17 Jan 2021 03:21:33



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-01-16T22:21:17', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '90261dbc-d861-4c6f-bb66-f268c61aa518'	System	17 Jan 2021 03:21:33
User entered 'No (N)'	System	17 Jan 2021 03:21:33

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-01-16T22:21:27', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '90261dbc-d861-4c6f-bb66-f268c61aa518'	System	17 Jan 2021 03:21:33
User entered '16 Jan 2021 22:21:27'	System	17 Jan 2021 03:21:33

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-01-27T11:52:34', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1eb02d95-efa9-492d-836f-83cc735c1160'	System	27 Jan 2021 16:53:22
User entered 'No (N)'	System	27 Jan 2021 16:53:22

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-01-27T11:53:06', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1eb02d95-efa9-492d-836f-83cc735c1160'	System	27 Jan 2021 16:53:22
User entered 'No (N)'	System	27 Jan 2021 16:53:22

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-01-27T11:53:15', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '1eb02d95-efa9-492d-836f-83cc735c1160'	System	27 Jan 2021 16:53:22
User entered '27 Jan 2021 11:53:15'	System	27 Jan 2021 16:53:22



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-02-03T20:47:35', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f4f53354-7af3-4d22-b868-674d774cc617'	System	04 Feb 2021 01:48:05
User entered 'No (N)'	System	04 Feb 2021 01:48:05

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-02-03T20:47:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f4f53354-7af3-4d22-b868-674d774cc617'	System	04 Feb 2021 01:48:05
User entered 'No (N)'	System	04 Feb 2021 01:48:05

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-02-03T20:47:58', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f4f53354-7af3-4d22-b868-674d774cc617'	System	04 Feb 2021 01:48:05
User entered '03 Feb 2021 20:47:58'	System	04 Feb 2021 01:48:05

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-02-10T14:18:30', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6c163d3a-a7ca-436d-9b4d-29e61af4fdbd'	System	10 Feb 2021 22:18:55
User entered 'No (N)'	System	10 Feb 2021 22:18:55

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-02-10T14:18:41', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6c163d3a-a7ca-436d-9b4d-29e61af4fdbd'	System	10 Feb 2021 22:18:55
User entered 'No (N)'	System	10 Feb 2021 22:18:55

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-02-10T14:18:49', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '6c163d3a-a7ca-436d-9b4d-29e61af4fdbd'	System	10 Feb 2021 22:18:55
User entered '10 Feb 2021 14:18:49'	System	10 Feb 2021 22:18:55

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-02-24T16:35:13', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '41a3ca72-e995-4de5-8489-fe9b38cf191f'	System	24 Feb 2021 21:35:38
User entered 'No (N)'	System	24 Feb 2021 21:35:38

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-02-24T16:35:20', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '41a3ca72-e995-4de5-8489-fe9b38cf191f'	System	24 Feb 2021 21:35:38
User entered 'No (N)'	System	24 Feb 2021 21:35:38

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-02-24T16:35:28', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '41a3ca72-e995-4de5-8489-fe9b38cf191f' User entered '24 Feb 2021 16:35:28'	System	24 Feb 2021 21:35:38
	System	24 Feb 2021 21:35:38

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-03-10T23:14:05', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f86db1a7-e5f3-45c1-aa49-72afaf7d42f6'	System	11 Mar 2021 04:15:34
User entered 'Yes (Y)'	System	11 Mar 2021 04:15:34

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-03-10T23:14:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f86db1a7-e5f3-45c1-aa49-72afaf7d42f6'	System	11 Mar 2021 04:15:34
User entered 'No (N)'	System	11 Mar 2021 04:15:34

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-03-10T23:15:02', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f86db1a7-e5f3-45c1-aa49-72afaf7d42f6'	System	11 Mar 2021 04:15:34
User entered 'No (N)'	System	11 Mar 2021 04:15:34

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-03-10T23:15:11', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f86db1a7-e5f3-45c1-aa49-72afaf7d42f6'	System	11 Mar 2021 04:15:34
User entered 'No (N)'	System	11 Mar 2021 04:15:34

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-03-10T23:15:23', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'f86db1a7-e5f3-45c1-aa49-72afaf7d42f6'	System	11 Mar 2021 04:15:34
User entered '10 Mar 2021 23:15:23'	System	11 Mar 2021 04:15:34



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-03-17T16:13:49', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '511118bb-a979-4d3b-8f6a-14921822084c'	System	17 Mar 2021 20:17:14
User entered 'No (N)'	System	17 Mar 2021 20:17:14

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-03-17T16:14:27', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '511118bb-a979-4d3b-8f6a-14921822084c'	System	17 Mar 2021 20:17:14
User entered 'No (N)'	System	17 Mar 2021 20:17:14

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-03-17T16:17:05', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '511118bb-a979-4d3b-8f6a-14921822084c' User entered '17 Mar 2021 16:17:05'	System	17 Mar 2021 20:17:14

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-03-24T18:26:37', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'fe3880f1-c095-4355-a6f2-015af6ac0aa1'	System	24 Mar 2021 22:26:55
User entered 'No (N)'	System	24 Mar 2021 22:26:55

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-03-24T18:26:42', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'fe3880f1-c095-4355-a6f2-015af6ac0aa1'	System	24 Mar 2021 22:26:55
User entered 'No (N)'	System	24 Mar 2021 22:26:55

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-03-24T18:26:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'fe3880f1-c095-4355-a6f2-015af6ac0aa1'	System	24 Mar 2021 22:26:55
User entered '24 Mar 2021 18:26:48'	System	24 Mar 2021 22:26:55

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-04-07T15:37:31', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '28e7fe8c-8bc7-43e2-9a1a-e0c2cade4ed0'	System	07 Apr 2021 19:37:56
User entered 'No (N)'	System	07 Apr 2021 19:37:56

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-04-07T15:37:44', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '28e7fe8c-8bc7-43e2-9a1a-e0c2cade4ed0'	System	07 Apr 2021 19:37:56
User entered 'No (N)'	System	07 Apr 2021 19:37:56

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-04-07T15:37:48', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '28e7fe8c-8bc7-43e2-9a1a-e0c2cade4ed0'	System	07 Apr 2021 19:37:56
User entered '07 Apr 2021 15:37:48'	System	07 Apr 2021 19:37:56

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-04-14T08:45:56', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd7ff2040-418a-47b4-b78d-190d7f7f6af1'	System	14 Apr 2021 17:05:21
User entered 'No (N)'	System	14 Apr 2021 17:05:21

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-04-14T08:46:00', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd7ff2040-418a-47b4-b78d-190d7f7f6af1'	System	14 Apr 2021 17:05:21
User entered 'No (N)'	System	14 Apr 2021 17:05:21

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-04-14T08:46:04', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'd7ff2040-418a-47b4-b78d-190d7f7f6af1'	System	14 Apr 2021 17:05:21
User entered '14 Apr 2021 08:46:04'	System	14 Apr 2021 17:05:21

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[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 (84cef305124fd0de)', Time: '2021-04-28T20:56:41', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '2b9e8f39-f745-4eac-a138-ad4647703fc3'	System	29 Apr 2021 00:56:57
User entered 'No (N)'	System	29 Apr 2021 00:56:57

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

Have you been exposed to someone with 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 (84cef305124fd0de)', Time: '2021-04-28T20:56:45', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '2b9e8f39-f745-4eac-a138-ad4647703fc3'	System	29 Apr 2021 00:56:57
User entered 'No (N)'	System	29 Apr 2021 00:56:57

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-04-28T20:56:50', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: '2b9e8f39-f745-4eac-a138-ad4647703fc3'	System	29 Apr 2021 00:56:57
User entered '28 Apr 2021 20:56:50'	System	29 Apr 2021 00:56:57

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:14:19



**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:14:19

**US3512272**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:14:19
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:14:19

US3512272

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:58:23

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)	24 Apr 2021 19:42:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-03-04T07:27:09', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bdf27648-0e4a-4421-85ac-7d2202d5167d'	System	04 Mar 2021 12:27:22
User entered 'No (N)'	System	04 Mar 2021 12:27:22

US3512272

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:58:23

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:42:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (84cef305124fd0de)', Time: '2021-03-04T07:27:14', User OID: 'PatientReportedOutcome (US3512272)', ODM File OID: 'bdf27648-0e4a-4421-85ac-7d2202d5167d'	System	04 Mar 2021 12:27:22
User entered '04 Mar 2021 07:27:14'	System	04 Mar 2021 12:27:22

**US3512272**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:46:31

**US3512272**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '9 Dec 2020'	Sheldon Warren (b) (4)	09 Dec 2020 21:46:31



**US3512272**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:46:31

US3512272

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:46:31

US3512272

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:46:37

**US3512272**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:01:50
User entered 'I'	System	09 Dec 2020 21:46:37

**US3512272**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	13 Jan 2021 17:53:58

**US3512272**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '13 Jan 2021'	Sheldon Warren (b) (4)	13 Jan 2021 17:53:58

**US3512272**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	13 Jan 2021 17:53:58

US3512272

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Sheldon Warren (b) (4)	13 Jan 2021 17:53:58



**US3512272**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	13 Jan 2021 17:54:02

**US3512272**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User entered 'I'	System	13 Jan 2021 17:54:02

**US3512272**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	09 Feb 2021 21:31:39

**US3512272**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '9 Feb 2021'	(b) (4) Sheldon Warren (b) (4)	09 Feb 2021 21:31:39

**US3512272**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	09 Feb 2021 21:31:39

US3512272

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Feb 2021 21:31:39

**US3512272**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	09 Feb 2021 21:31:45

**US3512272**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User entered 'I'	System	09 Feb 2021 21:31:45



**US3512272**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:54:28
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	11 Mar 2021 18:22:37

**US3512272**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:54:28
User entered '11 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	11 Mar 2021 18:22:37

**US3512272**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:58:23**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:54:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	11 Mar 2021 18:22:37

US3512272

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:54:28
User entered empty.	(b) (4) Sheldon Warren (b) (4)	11 Mar 2021 18:22:37

US3512272

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:54:28
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	11 Mar 2021 18:22:43

**US3512272**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:18:52
User entered 'I'	System	11 Mar 2021 18:22:43

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:38

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:38



US3512272

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:38

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 19:41:38

US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50

US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50

US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:41:50

US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50

US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50



US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:41:50

US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:41:50

US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:41:50

US3512272

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:50



**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:41:50

US3512272

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:56

US3512272

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:41:56

US3512272

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:42:14

US3512272

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:42:14

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:58:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered '15:36'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:42:14

**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:58:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 15:36'	System	13 Apr 2021 19:42:14

US3512272

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 19:42:19



**US3512272**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 19:42:19

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:58:23**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:26
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '11 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 20:54:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:58:23**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:26
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '13:06'	Sheldon Warren (b) (4)	15 Mar 2021 20:54:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:58:23**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:26
User entered '11 Mar 2021 13:06'	System	15 Mar 2021 20:54:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:58:23**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:26
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Safety Call (Safety Call)'	Sheldon Warren (b) (4)	15 Mar 2021 20:54:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:58:23**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:26
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	15 Mar 2021 20:54:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 1 (Day 1)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '3 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23



**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty; reason for change Data Entry Error	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:02:48
User entered 'na' (non-conformant).	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 20:59:23

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23



US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23



**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:58:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 20:59:23

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 2 (Day 2)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '4 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48



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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48



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Folder: Covid-19 Assessment 11 Mar 2021

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Generated On: 10 Jun 2021 07:58:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (2)**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (2)**

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48



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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:02:48

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 3 (Day 3)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '5 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09



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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09



**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:58:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:06:09



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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 4 (Day 4)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '6 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:08:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32



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Folder: Covid-19 Assessment 11 Mar 2021

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Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)' reason for change:	(b) (4)	
Data Entry Error	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12
User entered 'Moderate (Moderate)'	(b) (4)	
	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32
	(b) (4)	

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32



**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:08:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 5 (Day 5)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '7 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12



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Folder: Covid-19 Assessment 11 Mar 2021

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Generated On: 10 Jun 2021 07:58:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:10:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12



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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12



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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:10:12

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Folder: Covid-19 Assessment 11 Mar 2021

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 6 (Day 6)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:58:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '8 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32



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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 07:58:23**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:11:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32



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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 21:18:20
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32
	(b) (4)	

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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (6)**

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:58:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Severe (Severe)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:58:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32



**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:11:32

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 7 (Day 7)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '9 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:13:44

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44



US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44



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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (7)**

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

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Folder: Covid-19 Assessment 11 Mar 2021

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

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Folder: Covid-19 Assessment 11 Mar 2021

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44

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Folder: Covid-19 Assessment 11 Mar 2021

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:13:44



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 8 (Day 8)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '10 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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Form: Symptom Log (8)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:15:18

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Folder: Covid-19 Assessment 11 Mar 2021

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18



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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

**US3512272**

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**Generated On: 10 Jun 2021 07:58:23**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18



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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (8)**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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**Folder: Covid-19 Assessment 11 Mar 2021**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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**Folder: Covid-19 Assessment 11 Mar 2021**

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:15:18

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Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 9 (Day 9)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '11 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30



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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

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**Form: Symptom Log (9)**

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 07:58:23**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30



US3512272

Folder: Covid-19 Assessment 11 Mar 2021

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Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30



**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:16:30

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 10 (Day 10)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '12 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20



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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:18:20

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20



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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20



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**Folder: Covid-19 Assessment 11 Mar 2021**

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**Generated On: 10 Jun 2021 07:58:23**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:18:20

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 11 (Day 11)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '13 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27



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Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:58:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

US3512272

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27



**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:58:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

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**Generated On: 10 Jun 2021 07:58:23**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:58:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:19:27



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 12 (Day 12)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '14 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:58:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered empty.	System	15 Mar 2021 21:20:25

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25



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Folder: Covid-19 Assessment 11 Mar 2021

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

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Generated On: 10 Jun 2021 07:58:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25



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**Folder: Covid-19 Assessment 11 Mar 2021**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (12)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:20:25

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Day 13 (Day 13)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '15 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32



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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (13)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '99'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered '%'	System	15 Mar 2021 21:21:32

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**Generated On: 10 Jun 2021 07:58:23**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '98.2' F	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:58:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

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**Generated On: 10 Jun 2021 07:58:23**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32



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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Mild (Mild)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Moderate (Moderate)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (13)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'None (None)'	Sheldon Warren (b) (4)	15 Mar 2021 21:21:32

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 21:52:21

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '98'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21



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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered '%'	System	22 Mar 2021 21:52:21

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21



US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21



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Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:52:21

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '98'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered '%'	System	22 Mar 2021 21:53:00

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '97.5' F	(b) (4), (b) (6)	22 Mar 2021 21:53:00



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**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 07:58:23**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00



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Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 07:58:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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Form: Symptom Log (15)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:00



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 21:53:31

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '98'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered '%'	System	22 Mar 2021 21:53:31

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '97.5' F	(b) (4), (b) (6)	22 Mar 2021 21:53:31

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Folder: Covid-19 Assessment 11 Mar 2021

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31



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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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Form: Symptom Log (16)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31



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Form: Symptom Log (16)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:58:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:58:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:58:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:58:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:53:31

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12



US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '98'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered '%'	System	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '97.5' F	(b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12



US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 07:58:23**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12



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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 07:58:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 07:58:23**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (17)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:12

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Day 18 (Day 18)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '20 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '98'	(b) (4), (b) (6)	22 Mar 2021 21:54:39



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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User entered '%'	System	22 Mar 2021 21:54:39

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '95.7' F	(b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39



**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: Symptom Log (18)**

**Generated On: 10 Jun 2021 07:58:23**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39



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Generated On: 10 Jun 2021 07:58:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 07:58:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:31
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:54:39

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:58:23

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '15 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 20:56:55

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:58:23

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	15 Mar 2021 20:56:55

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:58:23

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User closed query 'Per CDM RQ: Response noted. Data is required and kindly consider to keep the query open till required data is updated.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:12:44
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
Query 'Per CDM RQ: Response noted. Data is required and kindly consider to keep the query open till required data is updated.' answered with 'updated' (Site from DM).	Allison Crain (b) (4)	26 Mar 2021 14:05:09
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Mar 2021 14:05:01
User opened query 'Per CDM RQ: Response noted. Data is required and kindly consider to keep the query open till required data is updated.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 05:51:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 05:49:41
Query 'Data is required. Please complete.' answered with 'data pending' (Site from System).	Sheldon Warren (b) (4)	15 Mar 2021 21:22:03
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 20:56:55
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 20:56:55

**US3512272**

**Folder: Covid-19 Assessment 11 Mar 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 07:58:23**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '15 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 20:56:55

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:58:23

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 20:56:55

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:58:23

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	Sheldon Warren (b) (4)	15 Mar 2021 20:56:55



US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:58:23

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	15 Mar 2021 20:56:55

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:58:23

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'The Legends Center Jacksonville'	Sheldon Warren (b) (4)	15 Mar 2021 20:56:55

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:58:23

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	15 Mar 2021 20:56:55

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:58:23

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:34
User entered '0'	System	26 Mar 2021 14:05:01

US3512272

Folder: Covid-19 Assessment 11 Mar 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:58:23

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:37
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'No (N)'	Allison Crain (b) (4)	26 Mar 2021 14:02:39

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50



**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

US3512272

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:58:23

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: saliva: PPD lab has not yet received the saliva sample dated 19MAR2021 for day 5, please confirm if the sample has been shipped, if yes provide accession ID/Tracking details.Thanks' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 08:06:08
Query 'Per GCL Lab Recon: saliva: PPD lab has not yet received the saliva sample dated 19MAR2021 for day 5, please confirm if the sample has been shipped, if yes provide accession ID/Tracking details.Thanks' answered with 'Sample is no longer stored on-site. The requisition label 1F621983857 was inadvertently entered into preclarus under US3512277 and a DCF was submitted to PPD on 17MAR2021. The Day 5 sample was not electronically requisitioned into preclarus prior to being inadvertently shipped from site. PPD was contacted and once the barcode number is confirmed, we will contact viracor to confirm sample was received.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 22:07:28
User opened query 'Per GCL Lab Recon: saliva: PPD lab has not yet received the saliva sample dated 19MAR2021 for day 5, please confirm if the sample has been shipped, if yes provide accession ID/Tracking details.Thanks' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 05:45:39
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered '19 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50



**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	22 Mar 2021 21:58:50



**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:58:50

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:22:33

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '15 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:22:33

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Clinic (Clinic)'	Sheldon Warren (b) (4)	15 Mar 2021 21:22:33

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered 'SICKD1'	System	15 Mar 2021 21:22:33

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:23:51

US3512272

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '15 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:23:51



**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '15:33'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:23:51

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered '15 Mar 2021 15:33'	System	15 Mar 2021 21:23:51

US3512272

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '66' in	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:23:51
DataPoint set to visible.	(b) (4) System	15 Mar 2021 21:22:33

US3512272

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '260' lb	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:23:51
DataPoint set to visible.	(b) (4) System	15 Mar 2021 21:22:33

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '98.2' F	Sheldon Warren (b) (4)	15 Mar 2021 21:23:51

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Oral (Oral)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:23:51

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:23:51

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '83'	Sheldon Warren (b) (4)	15 Mar 2021 21:23:51



**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered 'bpm'	System	15 Mar 2021 21:23:51

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '20'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:23:51

US3512272

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered 'breaths/min'	System	15 Mar 2021 21:23:51

US3512272

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '119'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:23:51

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered 'mmHg'	System	15 Mar 2021 21:23:51

US3512272

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '75'	Sheldon Warren (b) (4)	15 Mar 2021 21:23:51

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered 'mmHg'	System	15 Mar 2021 21:23:51

US3512272

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44



US3512272

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44

US3512272

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:24:00

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:58:23**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '15 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:24:00

US3512272

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:58:23

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:24:08

**US3512272**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 07:58:23**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '15 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:24:08

**US3512272**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:16

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:16

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:16



**US3512272**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	22 Mar 2021 21:59:16

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11

**US3512272**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 21:59:11

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11



US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11

**US3512272**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 21:59:11

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11

**US3512272**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 21:59:11

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11

**US3512272**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 21:59:11

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:11

**US3512272**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:58:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 21:59:11



US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:06

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:06

US3512272

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 07:58:23**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:01

US3512272

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:58:23

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:27:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:59:01

US3512272

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 14:10:30

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '28 Jan 2021'	Brenda Anderson (b) (4)	03 Feb 2021 14:10:30

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[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 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	03 Feb 2021 14:10:30

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:58:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 14:10:30



**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:58:23**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '28 Jan 2021'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:05

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:58:23**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
User entered '0'	(b) (4) Allison Crain (b) (4)	08 Apr 2021 13:42:37
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 15:10:10

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:58:23**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:05

US3512272

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:58:23

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:46:34
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 blank field.' (Site from DM).	(b) (4)	09 Apr 2021 06:03:51
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 blank field.' answered with 'updated' (Site from DM).	Allison Crain (b) (4)	08 Apr 2021 13:42:52
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	08 Apr 2021 13:42:37
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 blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:36:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:10:10

US3512272

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:58:23

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '28 Jan 2021'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:05

US3512272

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:58:23

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:05

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:58:23**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:05

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:58:23**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:05



**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:58:23**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:05

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:58:23**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	03 Feb 2021 14:11:05

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:58:23**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered empty.	System	03 Feb 2021 14:11:05

US3512272

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:25

US3512272

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '28 Jan 2021'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:25

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:58:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15:31'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:25

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:58:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '28 Jan 2021 15:31'	System	03 Feb 2021 14:11:25

US3512272

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:58:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:53



**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:58:23**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '28 Jan 2021'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:53

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:58:23**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '15:21'	Brenda Anderson (b) (4)	03 Feb 2021 14:11:53

**US3512272**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:58:23**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:48:53
User entered '28 Jan 2021 15:21'	System	03 Feb 2021 14:11:53

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 07:58:23**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sheldon Warren (b) (4)	09 Dec 2020 22:18:26
User entered 'No (N)'	(b) (4)	
	Brenda Anderson (b) (4)	17 Sep 2020 18:30:08
	(b) (4)	

US3512272

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:23

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Dec 2020 22:23:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 22:23:00
Data point term sent to Coder	System	09 Dec 2020 22:21:33
User entered 'worsening hypertension'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '9 Dec 2020'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 22:20:33

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

US3512272

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:23

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 22:20:33

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 22:20:33



US3512272

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

US3512272

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 22:20:33

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '1'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 22:20:33

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	09 Dec 2020 22:20:33
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 22:20:33

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 22:20:33

US3512272

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:23

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia aggravated - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Dec 2020 20:41:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 20:41:29
Data point term sent to Coder	System	28 Dec 2020 20:40:25
User entered 'worsening hypercholesterolemia'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '15 Dec 2020'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 20:40:22

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 20:40:22

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sheldon Warren (b) (4)	28 Dec 2020 20:40:22

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

US3512272

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

US3512272

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Sheldon Warren (b) (4) (b) (4)	28 Dec 2020 20:40:22

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sheldon Warren (b) (4)	28 Dec 2020 20:40:22



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '1'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Sheldon Warren (b) (4)	28 Dec 2020 20:40:22

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:40:22
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Dec 2020 20:40:22

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Dec 2020 20:40:22



US3512272

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:23

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Apr 2021 21:48:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:48:24
Data point term sent to Coder	System	06 Apr 2021 21:47:08
User entered 'Covid Like illness'	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:46:18

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '3 Mar 2021'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:46:18

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '17 Mar 2021'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:46:18

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

US3512272

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

US3512272

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

US3512272

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '1'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	06 Apr 2021 21:46:18
	(b) (4)	

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	08 Apr 2021 12:07:22
User entered empty.	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:46:18



**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 21:46:18

**US3512272**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 21:46:18

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:58:23

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User closed query 'Per CDM: Diary Dose 2 (1), Temperature day Log Lines 2and 3, ediary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please update the Concomitant Medications page with details of the medication taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 05:03:48
Query 'Per CDM: Diary Dose 2 (1), Temperature day Log Lines 2and 3, ediary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please update the Concomitant Medications page with details of the medication taken. ' answered with 'Added to Conmed list' (Site from DM).	Allison Crain (b) (4) (b) (4)	14 Nov 2020 14:30:55
User opened query 'Per CDM: Diary Dose 2 (1), Temperature day Log Lines 2and 3, ediary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please update the Concomitant Medications page with details of the medication taken. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:07:08
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 18:30:23

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS, PRODUCT: AMLODIPINE;BENAZEPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 18:32:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:32:46
Data point term sent to Coder	System	17 Sep 2020 18:31:49
User entered 'AMLODIPINE BENAZAPRIL'	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 18:31:05

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'HYPERTENSION'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '10' reason for change: New Information	Sheldon Warren (b) (4)	09 Dec 2020 22:17:08
	(b) (4)	
User entered '5/40' reason for change: Data Entry Error	Brenda Anderson (b) (4)	17 Sep 2020 18:31:58
	(b) (4)	
User entered '1'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	17 Sep 2020 18:31:58
	(b) (4)	
User entered 'capsule (CAPSULE)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'once daily (QD)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '9 Dec 2020' reason for change: New Information	Sheldon Warren (b) (4)	09 Dec 2020 22:17:08
	(b) (4)	
User entered 'UN UNK 2000'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	



US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:05
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:31:05

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:31:05

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 18:31:05

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 18:32:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:32:47
Data point term sent to Coder	System	17 Sep 2020 18:31:50
User entered 'ATORVASTATIN'	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 18:31:36

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'HIGH CHOLESTEROL'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '80' reason for change: New Information	Sheldon Warren (b) (4)	16 Dec 2020 18:33:23
	(b) (4)	
User entered '40'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'mg (mg)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'once daily (QD)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'UN UNK 1987'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:31:36
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:31:36

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:31:36

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 18:31:36

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 18:33:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:33:36
Data point term sent to Coder	System	17 Sep 2020 18:32:52
User entered 'METOPROLOL ER SUCCINATE'	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 18:32:49



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'HYPERTENSION'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '25'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'mg (mg)'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'once daily (QD)'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	



US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'UN UNK 2000'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:32:49
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:32:49

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:32:49



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 18:32:49

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 18:36:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 18:36:43
Data point term sent to Coder	System	17 Sep 2020 18:36:01
User entered 'MONTELUKAST'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'SEASONAL ALLERGIES'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '10'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'mg (mg)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'once daily (QD)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	



US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 18:35:01

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 22:26:06
User entered empty.	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 18:35:01

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'UN UNK 2016'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:01
	(b) (4)	



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:35:01

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:35:01

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 18:35:01

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:05:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:05:17
Data point term sent to Coder	System	27 Oct 2020 20:44:35
User entered 'VITAMIN B COMPLEX: THIAMINE HCL 5MG RIBOFLAVIN 5-PHOSPOHATE 10 MG NIACINAMIDE 30MG PYRIDOXAL-5 PHOSPHATE 10 MG B9 680MCG B12 24MCG B7 60MCG B5 10 MG' reason for change: Data Entry Error Coding entries removed.	Sheldon Warren (b) (4)	27 Oct 2020 20:44:29
User entered 'VITAMIN B COMPLEX Thiamine HCL 5mg Riboflavin 5-phosphohate 10 mg Niacinamide 30mg Pyridoxal-5 phosphate 10 mg B9 680mcg B12 24mcg B7 60mcg B5 10 mg' reason for change: Data Entry Error	Sheldon Warren (b) (4)	27 Oct 2020 20:44:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 12:08:38

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:36:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:36:43
Data point term sent to Coder	System	17 Sep 2020 18:36:00
User entered 'VITAMIN B COMPLEX'	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 18:35:39

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User closed query 'Per DM CLR - Requery: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease (see eCRF Guidelines V2.0 23Oct2020) page 40. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:18:15
Query 'Per DM CLR - Requery: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease (see eCRF Guidelines V2.0 23Oct2020) page 40. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	13 Nov 2020 12:56:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	13 Nov 2020 12:56:25
User opened query 'Per DM CLR - Requery: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease (see eCRF Guidelines V2.0 23Oct2020) page 40. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:43:41
User closed query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:43:41
Query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' answered with 'done' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	27 Oct 2020 20:41:46
User opened query 'Per DM CLR: Indication = SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:07:45
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 18:35:39

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EAB) (1725)

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**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'SUPPLEMENT'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '1'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User closed query 'Per CDM CR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 05:21:31
Query 'Per CDM CR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'done' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	27 Oct 2020 20:42:00
User opened query 'Per CDM CR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:07:59
User entered 'tablet (TABLET)'	Brenda Anderson (b) (4) (b) (4)	17 Sep 2020 18:35:39

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'once daily (QD)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '10 Sep 2020'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	17 Sep 2020 18:35:39
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:35:39

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:35:39

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 18:35:39

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 23:23:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 23:23:38
Data point term sent to Coder	System	24 Sep 2020 23:23:14
User entered 'ibuprofen'	Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'muscle aches'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '200'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'mg (mg)'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'once (ONCE)'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Oral (ORAL)'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '20 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '20 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	24 Sep 2020 23:22:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User entered empty.	System	24 Sep 2020 23:22:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User entered empty.	System	24 Sep 2020 23:22:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:23
User entered empty.	System	24 Sep 2020 23:22:20



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 14:32:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 14:32:49
Data point term sent to Coder	System	14 Nov 2020 14:31:32
User entered 'IBUPROFEN'	Allison Crain (b) (4)	14 Nov 2020 14:30:33

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	14 Nov 2020 14:30:33

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 05:24:31
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'did not meet AE reporting criteria' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	28 Dec 2020 20:37:05

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:30:10
User entered 'PAIN AT THE INJECTION SITE'	Allison Crain (b) (4) (b) (4)	14 Nov 2020 14:30:33

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '800'	(b) (4) Allison Crain (b) (4)	14 Nov 2020 14:30:33

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'mg (mg)'	(b) (4) Allison Crain (b) (4)	14 Nov 2020 14:30:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	14 Nov 2020 14:30:33

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'once daily (QD)'	(b) (4) Allison Crain (b) (4)	14 Nov 2020 14:30:33



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Allison Crain (b) (4)	14 Nov 2020 14:30:33

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Oral (ORAL)'	(b) (4) Allison Crain (b) (4)	14 Nov 2020 14:30:33

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	14 Nov 2020 14:30:33

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User closed query 'Per DM CLR: Please review Start date of this medication as this is before the occurrence of PAIN AT INJECTION SITE which started 16 Oct 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 05:27:50
Query 'Per DM CLR: Please review Start date of this medication as this is before the occurrence of PAIN AT INJECTION SITE which started 16 Oct 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' answered with 'Participant reported medication use following on same day as injection per follow up telephone call and in diary dose 2' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	28 Dec 2020 20:38:48
User opened query 'Per DM CLR: Please review Start date of this medication as this is before the occurrence of PAIN AT INJECTION SITE which started 16 Oct 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:31:45
User entered '15 Oct 2020'	Allison Crain (b) (4) (b) (4)	14 Nov 2020 14:30:33

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	(b) (4) Allison Crain (b) (4)	14 Nov 2020 14:30:33

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	14 Nov 2020 14:30:33

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:23**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '16 Oct 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	14 Nov 2020 14:30:33

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	14 Nov 2020 14:30:33



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User entered '1'	System	14 Nov 2020 14:30:33

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User entered '1'	System	14 Nov 2020 14:30:33

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:28
User entered '804 (804)'	System	14 Nov 2020 14:30:33

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 21:49:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 21:49:45
Data point term sent to Coder	System	09 Dec 2020 21:49:12
User entered 'influenza vaccine'	Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'seasonal influenza'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'I'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Other (OTHER)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'injection'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'once (ONCE)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '9 Dec 2020'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '0'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered '9 Dec 2020'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	09 Dec 2020 21:48:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User entered empty.	System	09 Dec 2020 21:48:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User entered empty.	System	09 Dec 2020 21:48:20

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:32
User entered empty.	System	09 Dec 2020 21:48:20

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL, PRODUCTSYNONYM: VITAMIN D2 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Jan 2021 15:20:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 15:20:19
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	29 Jan 2021 15:19:24 29 Jan 2021 15:19:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL, PRODUCTSYNONYM: VITAMIN D2 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 19:15:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 19:15:56
Data point term sent to Coder User entered 'vitamin D2'	System Sheldon Warren (b) (4)	16 Dec 2020 19:14:43 16 Dec 2020 19:13:59

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'ADDED TO MH' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:11:33
User entered 'VITAMIN D DEFICIENCY' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	29 Jan 2021 15:19:28
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). User entered 'low vitamin D'	(b) (4), (b) (6) Sheldon Warren (b) (4) (b) (4)	27 Jan 2021 05:22:09 16 Dec 2020 19:13:59



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '50000'	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'IU (IU)'	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'every week (QS)'	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '15 Dec 2020'	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	16 Dec 2020 19:13:59
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Dec 2020 19:13:59

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Dec 2020 19:13:59

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	16 Dec 2020 19:13:59

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Dec 2020 07:51:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 07:51:29
Data point term sent to Coder	System	28 Dec 2020 20:42:31
User entered 'atorvastatin'	Sheldon Warren (b) (4) (b) (4)	28 Dec 2020 20:41:58



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'worsening hypercholesterolemia'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '80'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'mg (mg)'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'once daily (QD)'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	



US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '15 Dec 2020'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	28 Dec 2020 20:41:58
	(b) (4)	

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 20:41:58

US3512272

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 20:41:58



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Dec 2020 20:41:58

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ANILIDES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:43:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:43:35
Data point term sent to Coder	System	06 Apr 2021 21:47:08
Coding entries removed.	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:46:50
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:46:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 08:55:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 08:55:56
Data point term sent to Coder	System	15 Mar 2021 21:37:32
User entered 'dayquil (acetaminophen 325mg, Dextromethorphan Hbr 15 mg, Doxylamine succinate 6.25 mg)'	Sheldon Warren (b) (4) (b) (4)	15 Mar 2021 21:36:44

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:47:00
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:46:57
Signature has been broken.	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:46:50
User entered 'COVID LIKE ILLNESS' reason for change: Per Query Resolution	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:46:50
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:07:22
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:46:10
User entered 'potential covid like illness'	Sheldon Warren (b) (4) (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'I'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'tablet (TABLET)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'as needed (PRN)'	Sheldon Warren (b) (4)	15 Mar 2021 21:36:44



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '5 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '12 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:36:44



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User entered empty.	System	15 Mar 2021 21:36:44

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User entered empty.	System	15 Mar 2021 21:36:44

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:41
User entered empty.	System	15 Mar 2021 21:36:44

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 04:57:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 04:57:36
Data point term sent to Coder	System	06 Apr 2021 21:48:09
Coding entries removed.	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:47:11
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:46:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 10:38:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 10:38:36
Data point term sent to Coder	System	15 Mar 2021 21:39:38
User entered 'nyquil ( acetaminophen 325 mg, Dextromethorphan hbr 10 mg, phenylephrine hcl 5 mg)'	Sheldon Warren (b) (4) (b) (4)	15 Mar 2021 21:38:40

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:47:09
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:47:18
Signature has been broken.	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:47:11
User entered 'COVID LIKE ILLNESS' reason for change: Per Query Resolution	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:47:11
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:08:57
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:46:10
User entered 'potential covid like illness'	Sheldon Warren (b) (4) (b) (4)	15 Mar 2021 21:38:40

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'I'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'tablet (TABLET)'	Sheldon Warren (b) (4)	15 Mar 2021 21:38:40



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'as needed (PRN)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '5 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '12 Mar 2021'	Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:38:40

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User entered empty.	System	15 Mar 2021 21:38:40

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User entered empty.	System	15 Mar 2021 21:38:40

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:45
User entered empty.	System	15 Mar 2021 21:38:40

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:48:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:48:25
Data point term sent to Coder Coding entries removed.	System Sheldon Warren (b) (4)	06 Apr 2021 21:48:09 06 Apr 2021 21:47:39
User signature succeeded.	(b) (4) Michael Koren (b) (4)	19 Mar 2021 20:46:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 21:41:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 21:41:33
Data point term sent to Coder User entered 'tylenol'	System Sheldon Warren (b) (4) (b) (4)	15 Mar 2021 21:40:41 15 Mar 2021 21:39:42

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:07:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:47:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:47:46
Signature has been broken.	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:47:39
User entered 'COVID LIKE ILLNESS' reason for change: Per Query Resolution	Sheldon Warren (b) (4) (b) (4)	06 Apr 2021 21:47:39
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:09:21
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:46:10
User entered 'potential covid like illness'	Sheldon Warren (b) (4) (b) (4)	15 Mar 2021 21:39:42



**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '2000'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'mg (mg)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'as needed (PRN)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'Oral (ORAL)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '3 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42



US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '0'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:23**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered '14 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

US3512272

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:46:10
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Mar 2021 21:39:42

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User entered empty.	System	15 Mar 2021 21:39:42

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User entered empty.	System	15 Mar 2021 21:39:42

**US3512272**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:27:50
User entered empty.	System	15 Mar 2021 21:39:42

US3512272

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 07:58:23**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 22:26:06
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	17 Sep 2020 18:37:19
	(b) (4)	