

US3662049 (Prod: Cincinnati CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:22:50

All time stamps listed in this document are displayed in GMT

**US3662049**

**Form: Participant Creation**

**Data signed:** (b) (4) 18 Mar 2021 21:45:49

**Generated On: 10 Jun 2021 09:22:50**

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[Participant ID](#)

US3662049

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

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**US3662049**

**Folder: Screening**

**Form: Visit Date**

**Data signed:** (b) (4) 18 Mar 2021 21:46:55

**Generated On: 10 Jun 2021 09:22:50**

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

US3662049

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Mar 2021 21:46:54

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	3 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

**US3662049**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Data signed:** (b) (4) 18 Mar 2021 21:46:54

**Generated On: 10 Jun 2021 09:22:50**

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

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Mar 2021 21:46:55

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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) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	PAIN MID LOWER BACK
Start date (dd MMM yyyy)	01 OCT 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	HYPERTROPHY OF PROSTATE
Start date (dd MMM yyyy)	09 AUG 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)	AUG 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	HYPERTONICITY OF BLADDER
Start date (dd MMM yyyy)	09 AUG 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)	AUG 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	URINARY FREQUENCY IN THE MORNING AND AT NIGHT
Start date (dd MMM yyyy)	15 APR 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)	APR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	PAIN LEFT EXTREMITIES JOINTS
Start date (dd MMM yyyy)	12 FEB 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)	FEB 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	BURNING IN EPIGASTRUM
Start date (dd MMM yyyy)	2 FEB 2020
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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	WEAKNESS MUSCLES LEFT EXTREMITIES
Start date (dd MMM yyyy)	12 FEB 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)	FEB 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	NUMBNESS LEFT EXTREMITIES
Start date (dd MMM yyyy)	12 FEB 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)	FEB 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	OTHER, SPECIFY DROPS THINGS A LOT WITH RIGHT HAND
Start date (dd MMM yyyy)	01 JUL 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)	JUL 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Mar 2021 21:46:54

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Condition	PLANTAR FASCIITIS WITH HEEL SPUR LEFT FOOT
Start date (dd MMM yyyy)	09 MAY 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	ANAL DYSPLASIA
Start date (dd MMM yyyy)	25 JUN 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	MEMORY LOSS
Start date (dd MMM yyyy)	26 AUG 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	FATIGUE
Start date (dd MMM yyyy)	26 AUG 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	UNSPECIFIED OSTEOPOROSIS
Start date (dd MMM yyyy)	26 AUG 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	CORNS AND CALLOSITIES, LEFT FOOT
Start date (dd MMM yyyy)	05 MAR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	UNSPECIFIED SEBORRHEIC DERMATITIS
Start date (dd MMM yyyy)	19 MAR 2008
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)	MAR 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	LIPODYSTROPHY
Start date (dd MMM yyyy)	06 FEB 2002
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)	FEB 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	INGUINAL HERNIA WITHOUT OBSTRUCTION/GANGRENE, BILATERAL
Start date (dd MMM yyyy)	04 OCT 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)	OCT 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	UNSPECIFIED ESSENTIAL HYPERTENSION
Start date (dd MMM yyyy)	04 OCT 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)	OCT 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	HYPOGONADISM
Start date (dd MMM yyyy)	20 OCT 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	DEPRESSIVE DISORDER NEC
Start date (dd MMM yyyy)	01 JUL 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	OTHER AND UNSPECIFIED HYPERLIPIDEMIA
Start date (dd MMM yyyy)	10 FEB 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Condition	HUMAN IMMUNODEFICIENCY VIRUS
Start date (dd MMM yyyy)	18 JUN 1996
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)	JUN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 21:46:55

Generated On: 10 Jun 2021 09:22:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:10
Height (xxx.x)	164.5 cm
Weight (xxx.x)	83.1 kg
BMI (xxx.x)	30.70925 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:46:55

Generated On: 10 Jun 2021 09:22:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 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: Risk of Exposure

Data signed: (b) (4) 18 Mar 2021 21:46:55

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Mar 2021 21:46:55

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 188608

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 ☐

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 18 Mar 2021 21:46:56

**Generated On: 10 Jun 2021 09:22:50**

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:10
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	16:12 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 16:12
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:46:56

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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) 18 Mar 2021 21:46:56

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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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 15:43 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 15:43

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

US3662049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 SEP 2020
Collection time (00:00-23:59)	14:50 (24 HR)
Collection date and time (derived)	03 SEP 2020 14:50

US3662049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:45	03 SEP 2020 14:45
Nasopharyngeal Swab 2	No		

US3662049

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

03 SEP 2020 16:16

PC Open Date & Time

03 SEP 2020 16:03

PC Close Date & Time

03 SEP 2020 18:33

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °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	03 SEP 2020 19:52
PC Open Date & Time	03 SEP 2020 19:28
PC Close Date & Time	04 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 16:55

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

05 SEP 2020 19:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 16:07

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:50

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

07 SEP 2020 15:49

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 6

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

08 SEP 2020 18:55

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:50

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**TIMEPOINT**

DAY 7

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.6 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

09 SEP 2020 16:45

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PC Open Date & Time

09 SEP 2020 12:00

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PC Close Date & Time

10 SEP 2020 11:59

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US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 16:15

PC Open Date & Time

03 SEP 2020 16:03

PC Close Date & Time

03 SEP 2020 18:33

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:53

PC Open Date & Time

03 SEP 2020 19:28

PC Close Date & Time

04 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 16:56

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 19:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 16:08

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 15:49

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 18:56

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:46

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 16:15
PC Open Date & Time	03 SEP 2020 16:03
PC Close Date & Time	03 SEP 2020 18:33

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 19:53
PC Open Date & Time	03 SEP 2020 19:28
PC Close Date & Time	04 SEP 2020 11:59



US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 16:56
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:07
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 16:08
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 15:50
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 18:56
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

		Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 16:46	
PC Open Date & Time	09 SEP 2020 12:00	
PC Close Date & Time	10 SEP 2020 11:59	

US3662049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3662049**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Data signed:** (b) (4) 18 Mar 2021 21:45:50

**Generated On: 10 Jun 2021 09:22:50**

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3662049**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Data signed:** (b) (4) 18 Mar 2021 21:45:50

**Generated On: 10 Jun 2021 09:22:50**

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3662049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3662049

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3662049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:50
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3662049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 13:22
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3662049

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3662049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 30 SEP 2020

What was the treatment time? (00:00-23:59) 12:49 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 12:49

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

US3662049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	12:00 (24 HR)
Collection date and time (derived)	30 SEP 2020 12:00



US3662049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:55	30 SEP 2020 11:55
Nasopharyngeal Swab 2	No		

US3662049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.8 °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 30 SEP 2020 13:25

PC Open Date & Time 30 SEP 2020 13:09

PC Close Date & Time 30 SEP 2020 15:39

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	30 SEP 2020 19:08
PC Open Date & Time	30 SEP 2020 16:34
PC Close Date & Time	01 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

01 OCT 2020 18:08

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 16:47

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

04 OCT 2020 08:47

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 21:20

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 16:49

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

06 OCT 2020 20:10

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 13:26

PC Open Date & Time

30 SEP 2020 13:09

PC Close Date & Time

30 SEP 2020 15:39

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 19:08

PC Open Date & Time

30 SEP 2020 16:34

PC Close Date & Time

01 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

1

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

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 18:09

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 16:47

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 08:48

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 21:20

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 16:49

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 20:10

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 13:26
PC Open Date & Time	30 SEP 2020 13:09
PC Close Date & Time	30 SEP 2020 15:39

US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 19:08
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PC Open Date & Time	30 SEP 2020 16:34
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PC Close Date & Time	01 OCT 2020 11:59
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US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 18:10
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59



US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

		Yes <input type="checkbox"/>
PC Time stamp	02 OCT 2020 16:48	
PC Open Date & Time	02 OCT 2020 12:00	
PC Close Date & Time	03 OCT 2020 11:59	

US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 08:48
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 21:21
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 16:50
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59



US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 20:11
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3662049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3662049

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3662049

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3662049**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 18 Mar 2021 21:45:50

**Generated On: 10 Jun 2021 09:22:50**

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3662049**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Data signed:** (b) (4) 18 Mar 2021 21:45:50

**Generated On: 10 Jun 2021 09:22:50**

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3662049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3662049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 10:15
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662049

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3662049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	10:20 (24 HR)
Collection date and time (derived)	28 OCT 2020 10:20

US3662049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:46:56

Generated On: 10 Jun 2021 09:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3662049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 10:39:58

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59



US3662049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	17 NOV 2020 11:13:19
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 14:03:59
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 08:54:51

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 DEC 2020 19:34:46
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 08:17:50

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 11:54:50

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 10:25:58

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 07:00:44

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59



US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 JAN 2021 06:45:15

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 10:03:47

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 07:36:31

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 08:03:30

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 15:52:10

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 FEB 2021 14:06:07
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 08:39:28

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 180

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

No ☒

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 MAR 2021 11:58:51

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59



US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 07:54:05

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 MAR 2021 11:29:20
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 13:13:11

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 10:56:11

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 10:32:44

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	13 APR 2021 10:20:47
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 11:04:13

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 APR 2021 10:57:06
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59



US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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15 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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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 278

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 292

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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19 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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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 313

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59



US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 383

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 390

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 467

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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18 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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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 481

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 565
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 593

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 649

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 656

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 670

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59



US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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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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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	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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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 733

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 747

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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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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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59

US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

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

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

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[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

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US3662049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:50

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3662049**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

05 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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**US3662049**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:22:50**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 11:58:39

US3662049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:46:54

Generated On: 10 Jun 2021 09:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3662049**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Data signed:** (b) (4) 18 Mar 2021 21:46:54

**Generated On: 10 Jun 2021 09:22:50**

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3662049**

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

**Form: Safety Call**

**Data signed:** (b) (4) 18 Mar 2021 21:45:50

**Generated On: 10 Jun 2021 09:22:50**

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3662049**

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

**Form: Continuing**

**Data signed:** (b) (4) 18 Mar 2021 21:45:50

**Generated On: 10 Jun 2021 09:22:50**

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3662049**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Data signed:** (b) (4) 18 Mar 2021 21:45:50

**Generated On: 10 Jun 2021 09:22:50**

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3662049**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Data signed:** (b) (4) 18 Mar 2021 21:45:50

**Generated On: 10 Jun 2021 09:22:50**

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 21:50:27

Generated On: 10 Jun 2021 09:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3662049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 21:50:27

Generated On: 10 Jun 2021 09:22:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 MAR 2021
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 09:59
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662049

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 21:50:27

Generated On: 10 Jun 2021 09:22:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3662049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 21:50:27

Generated On: 10 Jun 2021 09:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 MAR 2021
Collection time (00:00-23:59)	10:05 (24 HR)
Collection date and time (derived)	29 MAR 2021 10:05

US3662049

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:50:27

Generated On: 10 Jun 2021 09:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:53:50

Generated On: 10 Jun 2021 09:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3662049

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:53:50

Generated On: 10 Jun 2021 09:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3662049**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3662049**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3662049**

**Folder: Covid-19 Assessment (2)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:22:50**

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Date of Contact	9 APR 2021
Time of Contact	08:00
Date and Time of Contact (derived)	9 APR 2021 08:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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	31 MAR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>



US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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	1 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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	2 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>



US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>



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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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 APR 2021
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>



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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>



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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

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"/>

US3662049

Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 09 Apr 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Date of Visit	9 APR 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	9 APR 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	UC HEALTH
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

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

**Data signed: (b) (4) 28 Apr 2021 13:39:29**

**Generated On: 10 Jun 2021 09:22:50**

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 28 Apr 2021 13:39:30

**Generated On: 10 Jun 2021 09:22:50**

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
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)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:39:30

Generated On: 10 Jun 2021 09:22:50

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD1



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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 13:39:30

Generated On: 10 Jun 2021 09:22:50

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3662049

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:39:30

Generated On: 10 Jun 2021 09:22:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3662049

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 13:39:30

Generated On: 10 Jun 2021 09:22:50

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Data signed:** (b) (4) 28 Apr 2021 13:39:29

**Generated On: 10 Jun 2021 09:22:50**

---

Was this visit performed? Yes ☐  
No ☒

---

Visit date (dd MMM yyyy) \_\_\_\_\_

---

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

---

Folder OID SICKD28

---

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3662049

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3662049

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3662049

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

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 JAN 2021
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



US3662049

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 19:03:15

Generated On: 10 Jun 2021 09:22:50

Date of updated informed consent (*dd MMM yyyy*) 6 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*) 6 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 \_\_\_\_\_

US3662049

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00-23:59)	14:05 (24 HR)
Collection date and time (derived)	6 JAN 2021 14:05

US3662049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	14:00
Collection Date and Time (derived)	6 JAN 2021 14:00

US3662049

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 19:03:15

Generated On: 10 Jun 2021 09:22:50

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:50

AEID	USA-US088-2021-MRNA-1273-P30 1000011
Adverse event	HYPOTENSION WITH NEAR SYNCOPE
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 APR 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)	9 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 APR 2021
Hospital Discharge Date (dd MMM yyyy)	10 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:50

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	

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Folder: Adverse Events

Form: Adverse Events (1)

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PATIENT WITH 3 WEEK  
HISTORY OF WORSENING  
DYSPNEA WITH EXERTION  
AND RECENT PROGRESSION TO  
SHORTNESS OF BREATH WHEN  
LYING DOWN. BEDSIDE ECHO  
DEMONSTRATED A CONCERN  
FOR RIGHT HEART STRAIN;  
HOWEVER CTPA NEGATIVE  
FOR PE. CHEST XRAY WITH NO  
ACUTE CARDIOPULMONARY  
ABNORMALITIES. PATIENT HAS  
RECEIVED BOTH DOSE OF  
COVID VACCINE. CBC, LDH,  
AND CK WITHIN NORMAL  
LIMITS. ANA AND ALDOLASE  
STUDIES PENDING AT  
DISCHARGE. FORMAL ECHO TO  
BE OBTAINED OUTPATIENT AS  
SOON AS IT CAN BE  
SCHEDULED.  
HYPOTENSION,  
LIGHTHEADEDNESS. PATIENT  
RECORDED HYPOTENSION AT  
HOME AND WAS ENCOURAGED  
TO COME INTO THE HOSPITAL.  
NORMO/HYPERTENSIVE IN THE  
EMERGENCY DEPARTMENT.  
PATIENT'S HISTORY OF  
LIGHTHEADEDNESS IN  
ACCORDANCE WITH  
ORTHOSTASIS. THOUGHT TO  
BE ASSOCIATED WITH THE  
INCREASED, LOOSE BOWEL  
MOVEMENTS AS DESCRIBED  
BELOW. PATIENT TREATED  
WITH IV FLUIDS WITH

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:50

IMPROVEMENT OF SYMPTOMS.  
HE WAS NOT ORTHOSTATIC.  
DOXAZOSIN WAS  
DISCONTINUED DUE TO THIS  
CONCERN.  
DIARRHEA. ENDORSES A FIVE  
DAY HISTORY OF 7-8 LOOSE  
STOOLS A DAY WITHOUT  
ABDOMINAL PAIN, MELENA OR  
HEMATOCHEZIA. ETIOLOGY  
UNCLEAR. O&P, ENTERIC  
PATHOGEN PANEL, C DIF  
PENDING AT DISCHARGE.  
WILL UPDATE AE AND  
PROCEDURE LOG.  
4/19/21 AFTER REVIEW OF  
HOSPITAL RECORDS AND F/U  
WITH PI, SAE TERM UPDATED  
TO HYPOTENSION WITH NEAR  
SYNCOPE PER PI INSTRUCTION.  
PARTICIPANT TOOK  
LISINOPRIL AND DOXAZOSIN  
TOGETHER AND PI FEELS THIS  
IS WHAT CAUSED THE  
HYPOTENSION WITH NEAR  
SYNCOPE.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:50

AEID	
Adverse event	ACUTE RENAL INJURY
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 APR 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)	10 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:50

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	True
Concomitant Medication	False
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)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:50

AEID

Adverse event

ORTHOPNEA

Was this a medically-attended AE?

Yes ☒  
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐  
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐  
No ☒

Start date (dd MMM yyyy)

2 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒  
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒  
Grade 2/Moderate ☐  
Grade 3/Severe ☐  
Grade 4 ☐

Is the adverse event serious?

Yes ☐  
No ☒

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 ☐  
No ☐  
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:50

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	True
Concomitant Medication	False
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)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:50

AEID	
Adverse event	DIARRHEA
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)	31 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)	10 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:50

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 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Mar 2021 21:45:50

Generated On: 10 Jun 2021 09:22:50

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication BURNING IN EPIGASTRUM

Dose per administration 40

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) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 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) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication TRAZODONE HCl

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 50

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) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	3 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication FLOMAX

Prophylaxis Yes ☐  
No ☒

Indication OVERACTIVE BLADDER

Dose per administration .8

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) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication PRAVASTATIN SODIUM

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input 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) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication ASCORBIC ACID

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JUL 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input 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) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication MULTI VITAMINS

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:39:29

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Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication ANDROGEL

Prophylaxis Yes ☐  
No ☒

Indication HYPOGONADISM

Dose per administration 50

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 (8)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 JUL 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

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) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 OCT 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication BIKTARVY

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 50/200/25

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 (10)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input 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) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication TRAZODONE HCL

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSIVE DISORDER

Dose per administration 100

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication DOXAZOSIN MESYLATE

Prophylaxis Yes ☐  
No ☒

Indication OVERACTIVE BLADDER

Dose per administration 4

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 (12)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 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)		9 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication OMNIPAQUE

Prophylaxis Yes ☐  
No ☒

Indication PROCEDURE

Dose per administration 255

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 (13)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	9 APR 2021	
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"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication DOXAZOSIN MESYLATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION/OVERACTIVE  
BLADDER

Dose per administration 8

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 (14)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (15)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication DIARRHEA

Dose per administration 4

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 (15)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 2021
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication DIARRHEA

Dose per administration 40

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

If dose unit is Other, specify MEQ

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 (16)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 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 (17)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication HEPARIN

Prophylaxis Yes ☒  
No ☐

Indication BLOOD CLOT PREVENTION

Dose per administration 5000

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication HYPOTENSION

Dose per administration 100

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

If dose unit is Other, specify ML/HR

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	10 APR 2021	
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"/>	

US3662049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 13:39:29

Generated On: 10 Jun 2021 09:22:50

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 13:39:29

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Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
9 APR 2021	ECG	Adverse Event	
14 APR 2021	ECHO 2D COMPLETE	Adverse Event	
9 APR 2021	CXR PA LATERAL	Adverse Event	
9 APR 2021	BEDSIDE FOCUSED TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	
9 APR 2021	CT PULMONARY ANGIOGRAPHY	Adverse Event	

US3662049

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:22:50

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3662049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:22:50

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3662049

Folder: SAE USA-US088-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 13:39:30

Generated On: 10 Jun 2021 09:22:50

SAEID	USA-US088-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4



US3662049

Folder: SAE USA-US088-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 13:39:30

Generated On: 10 Jun 2021 09:22:50

SAEID	USA-US088-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 15:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3662049

Folder: SAE USA-US088-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 13:39:30

Generated On: 10 Jun 2021 09:22:50

SAEID	USA-US088-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 06:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3662049

Folder: SAE USA-US088-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 13:39:30

Generated On: 10 Jun 2021 09:22:50

SAEID	USA-US088-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/APR/2021 17:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3662049

Folder: SAE USA-US088-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 13:39:30

Generated On: 10 Jun 2021 09:22:50

SAEID	USA-US088-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/APR/2021 12:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3662049 (Prod: Cincinnati CRS)

**US3662049**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:22:50**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'US3662049'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:14:49

**US3662049**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:21:49

US3662049

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User closed query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete all applicable forms for this visit.' answered with 'All applicable forms completed for this visit' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 05:12:57
User opened query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	Brenda Miller (b) (4)	12 Sep 2020 16:21:40
User entered '03 SEP 2020'	(b) (4)	
	(b) (4), (b) (6)	08 Sep 2020 10:44:04
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	03 Sep 2020 18:14:50



**US3662049**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	12 Sep 2020 16:21:49

**US3662049**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'SCRN'	System	12 Sep 2020 16:21:49

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:14:51

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '65'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'YEARS'	System	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '65'	System	03 Sep 2020 19:00:17

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Male (M)'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25



**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'I'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25



**US3662049**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:50**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 15:59:25

**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '3 Sep 2020'	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:00:17

**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Sep 2020'	System	03 Sep 2020 19:00:17

**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2020'	System	03 Sep 2020 19:00:17

**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Amendment 3 (3)'	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:00:17

**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:00:17

**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:00:17

**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:00:17



**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:00:17

**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:14:50

**US3662049**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:50**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'I'	System	03 Sep 2020 19:00:26

**US3662049**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:00:26

**US3662049**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:22:50**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 15:59:56

US3662049

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Sep 2020 05:49:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:49:42
Data point term sent to Coder	System	12 Sep 2020 16:01:58
User entered 'Pain Mid Lower Back'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:01:04

**US3662049**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '01 Oct 2017'	Brenda Miller (b) (4)	12 Sep 2020 16:01:04

**US3662049**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:01:04



**US3662049**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:01:04

**US3662049**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:01:04

**US3662049**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:01:04

**US3662049**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Oct 2017'	System	12 Sep 2020 16:01:04

**US3662049**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2017'	System	12 Sep 2020 16:01:04

**US3662049**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:01:04

**US3662049**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:01:04

US3662049

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 05:27:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 05:27:46
Data point term sent to Coder	System	12 Sep 2020 16:01:57
User entered 'Hypertrophy of Prostate'	Brenda Miller (b) (4)	12 Sep 2020 16:01:38



**US3662049**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '09 Aug 2016'	Brenda Miller (b) (4)	12 Sep 2020 16:01:38

**US3662049**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:01:38

**US3662049**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:01:38

**US3662049**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:01:38

**US3662049**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:01:38

**US3662049**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Aug 2016'	System	12 Sep 2020 16:01:38

**US3662049**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2016'	System	12 Sep 2020 16:01:38

**US3662049**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:01:38



**US3662049**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:01:38

US3662049

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Hypertonicity of bladder - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 16:03:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:03:49
Data point term sent to Coder	System	12 Sep 2020 16:03:02
User entered 'Hypertonicity of Bladder'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:02:06

**US3662049**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '09 Aug 2016'	Brenda Miller (b) (4)	12 Sep 2020 16:02:06

**US3662049**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:02:06

**US3662049**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:02:06

**US3662049**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:02:06

**US3662049**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:02:06

**US3662049**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Aug 2016'	System	12 Sep 2020 16:02:06



**US3662049**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2016'	System	12 Sep 2020 16:02:06

**US3662049**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:02:06

**US3662049**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:02:06

US3662049

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urinary frequency - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Sep 2020 06:02:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 06:02:44
Data point term sent to Coder	System	12 Sep 2020 16:03:02
User entered 'Urinary Frequency in the morning and at night'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:02:34

**US3662049**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '15 Apr 2016'	Brenda Miller (b) (4)	12 Sep 2020 16:02:34

**US3662049**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:02:34

**US3662049**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Sep 2020 16:22:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	12 Sep 2020 16:22:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	12 Sep 2020 16:02:34
	Brenda Miller (b) (4)	12 Sep 2020 16:02:34
	(b) (4)	

**US3662049**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:02:34



**US3662049**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:02:34

**US3662049**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Apr 2016'	System	12 Sep 2020 16:02:34

**US3662049**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2016'	System	12 Sep 2020 16:02:34

**US3662049**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:02:34

**US3662049**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:02:34

US3662049

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Sep 2020 05:49:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:49:42
Data point term sent to Coder	System	12 Sep 2020 16:05:06
User entered 'Pain Left Extremities Joints'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:04:55

**US3662049**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '12 Feb 2016'	Brenda Miller (b) (4)	12 Sep 2020 16:04:55

**US3662049**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:04:55



**US3662049**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:04:55

**US3662049**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:04:55

**US3662049**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:04:55

**US3662049**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Feb 2016'	System	12 Sep 2020 16:04:55

**US3662049**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2016'	System	12 Sep 2020 16:04:55

**US3662049**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:04:55

**US3662049**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:04:55

US3662049

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Epigastric burning - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Oct 2020 09:56:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:56:42
Data point term sent to Coder	System	16 Oct 2020 20:20:32
User entered 'burning in epigastrium'	michelle saemann (b) (4) (b) (4)	16 Oct 2020 20:19:55



**US3662049**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '2 Feb 2020'	(b) (4) michelle saemann (b) (4)	16 Oct 2020 20:19:55

**US3662049**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	(b) (4) michelle saemann (b) (4)	16 Oct 2020 20:19:55

**US3662049**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	16 Oct 2020 20:19:55

**US3662049**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	(b) (4) michelle saemann (b) (4)	16 Oct 2020 20:19:55

**US3662049**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	(b) (4) michelle saemann (b) (4)	16 Oct 2020 20:19:55

**US3662049**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Feb 2020'	System	16 Oct 2020 20:19:55

**US3662049**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2020'	System	16 Oct 2020 20:19:55

**US3662049**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	16 Oct 2020 20:19:55



**US3662049**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	16 Oct 2020 20:19:55

US3662049

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle weakness conditions, PT: Muscular weakness, LLT: Weakness in extremity - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 06:06:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 06:06:50
Data point term sent to Coder	System	12 Sep 2020 16:06:08
User entered 'Weakness Muscles Left Extremities'	Brenda Miller (b) (4)	12 Sep 2020 16:05:33

**US3662049**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '12 Feb 2016'	Brenda Miller (b) (4)	12 Sep 2020 16:05:33

**US3662049**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:05:33

**US3662049**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:05:33

**US3662049**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:05:33

**US3662049**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:05:33

**US3662049**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Feb 2016'	System	12 Sep 2020 16:05:33



**US3662049**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2016'	System	12 Sep 2020 16:05:33

**US3662049**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:05:33

**US3662049**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:05:33

US3662049

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Hypoaesthesia, LLT: Numbness of extremities - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Sep 2020 05:47:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:47:40
Data point term sent to Coder	System	12 Sep 2020 16:07:13
User entered 'Numbness Left Extremities'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:06:21

**US3662049**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '12 Feb 2016'	Brenda Miller (b) (4)	12 Sep 2020 16:06:21

**US3662049**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:06:21

**US3662049**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:06:21

**US3662049**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:06:21



**US3662049**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:06:21

**US3662049**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Feb 2016'	System	12 Sep 2020 16:06:21

**US3662049**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2016'	System	12 Sep 2020 16:06:21

**US3662049**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:06:21

**US3662049**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:06:21

US3662049

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User closed query 'Per MM, please review and update the term to reflect the underlying etiology if known. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:32:07
Query 'Per MM, please review and update the term to michelle saemann reflect the underlying etiology if known. ' answered with 'underlying etiology not known. ' (Site from DM).	(b) (4) (b) (4)	06 Oct 2020 00:55:34
User opened query 'Per MM, please review and update the term to reflect the underlying etiology if known. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:16:12
Query 'Per MM, please review and amend the term 'INGUINAL HERNIA WITHOUT OBSTRUCTION/ GANGRNE' ' canceled (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:14:04
User opened query 'Per MM, please review and amend the term 'INGUINAL HERNIA WITHOUT OBSTRUCTION/ GANGRNE' ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:12:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthropathy, LLT: Unspecified disorder of hand joint - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 11:35:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 11:35:49
Data point term sent to Coder	System	12 Sep 2020 16:08:13
User entered 'Other, Specify Drops Things a Lot With Right Hand'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:07:22

**US3662049**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '01 Jul 2015'	Brenda Miller (b) (4)	12 Sep 2020 16:07:22

**US3662049**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:07:22



**US3662049**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:07:22

**US3662049**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:07:22

**US3662049**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:07:22

**US3662049**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Jul 2015'	System	12 Sep 2020 16:07:22

**US3662049**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2015'	System	12 Sep 2020 16:07:22

**US3662049**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:07:22

**US3662049**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:07:22

US3662049

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Plantar fasciitis, LLT: Plantar fasciitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Sep 2020 05:51:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:51:43
Data point term sent to Coder	System	12 Sep 2020 16:09:16
User entered 'Plantar Fasciitis with Heel Spur Left Foot'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:09:05



**US3662049**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '09 May 2014'	Brenda Miller (b) (4)	12 Sep 2020 16:09:05

**US3662049**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:09:05

**US3662049**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:09:05

**US3662049**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:09:05

**US3662049**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:09:05

**US3662049**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'May 2014'	System	12 Sep 2020 16:09:05

**US3662049**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2014'	System	12 Sep 2020 16:09:05

**US3662049**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:09:05



**US3662049**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:09:05

US3662049

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Gastrointestinal disorders, HLGT: Anal and rectal conditions NEC, HLT: Anal and rectal disorders NEC, PT: Anogenital dysplasia, LLT: Anal dysplasia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 16:11:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:11:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Anal and rectal conditions NEC, HLT: Anal and rectal disorders NEC, PT: Anogenital dysplasia, LLT: Anal dysplasia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:10:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:10:58
Data point term sent to Coder	System	12 Sep 2020 16:10:23
User entered 'Anal Dysplasia'	Brenda Miller (b) (4)	12 Sep 2020 16:09:43
	(b) (4)	

**US3662049**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '25 Jun 2013'	Brenda Miller (b) (4)	12 Sep 2020 16:09:43

**US3662049**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:09:43

**US3662049**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:09:43

**US3662049**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:09:43

**US3662049**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:09:43

**US3662049**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Jun 2013'	System	12 Sep 2020 16:09:43



**US3662049**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2013'	System	12 Sep 2020 16:09:43

**US3662049**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:09:43

**US3662049**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:09:43

US3662049

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Memory loss (excl dementia), PT: Amnesia, LLT: Memory loss - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:10:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:10:59
Data point term sent to Coder	System	12 Sep 2020 16:10:24
User entered 'Memory Loss'	Brenda Miller (b) (4)	12 Sep 2020 16:10:17

**US3662049**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '26 Aug 2010'	Brenda Miller (b) (4)	12 Sep 2020 16:10:17

**US3662049**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:10:17

**US3662049**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:10:17

**US3662049**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:10:17



**US3662049**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:10:17

**US3662049**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Aug 2010'	System	12 Sep 2020 16:10:17

**US3662049**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2010'	System	12 Sep 2020 16:10:17

**US3662049**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:10:17

**US3662049**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:10:17

US3662049

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:11:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:11:49
Data point term sent to Coder	System	12 Sep 2020 16:11:29
User entered 'Fatigue'	Brenda Miller (b) (4)	12 Sep 2020 16:10:46

**US3662049**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '26 Aug 2010'	Brenda Miller (b) (4)	12 Sep 2020 16:10:46

**US3662049**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:10:46



**US3662049**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:10:46

**US3662049**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:10:46

**US3662049**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:10:46

**US3662049**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Aug 2010'	System	12 Sep 2020 16:10:46

**US3662049**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2010'	System	12 Sep 2020 16:10:46

**US3662049**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:10:46

**US3662049**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:10:46

US3662049

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis, unspecified - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 16:11:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:11:50
Data point term sent to Coder	System	12 Sep 2020 16:11:30
User entered 'Unspecified Osteoporosis'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:11:12



**US3662049**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '26 Aug 2009'	Brenda Miller (b) (4)	12 Sep 2020 16:11:12

**US3662049**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:11:12

**US3662049**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:11:12

**US3662049**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:11:12

**US3662049**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:11:12

**US3662049**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Aug 2009'	System	12 Sep 2020 16:11:12

**US3662049**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2009'	System	12 Sep 2020 16:11:12

**US3662049**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:11:12



**US3662049**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:11:12

US3662049

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Hyperkeratoses, PT: Hyperkeratosis, LLT: Callosities - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 20:41:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 20:41:40
Data point term sent to Coder	System	12 Sep 2020 16:12:35
User entered 'Corns and Callosities, Left Foot'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:11:54

**US3662049**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '05 Mar 2009'	Brenda Miller (b) (4)	12 Sep 2020 16:11:54

**US3662049**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:11:54

**US3662049**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:11:54

**US3662049**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:11:54

**US3662049**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:11:54

**US3662049**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Mar 2009'	System	12 Sep 2020 16:11:54



**US3662049**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2009'	System	12 Sep 2020 16:11:54

**US3662049**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:11:54

**US3662049**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:11:54

US3662049

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Seborrhoeic dermatitis, LLT: Seborrheic dermatitis, unspecified - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 06:02:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 06:02:44
Data point term sent to Coder	System	12 Sep 2020 16:12:35
User entered 'Unspecified Seborrheic Dermatitis'	Brenda Miller (b) (4)	12 Sep 2020 16:12:26

**US3662049**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '19 Mar 2008'	Brenda Miller (b) (4)	12 Sep 2020 16:12:26

**US3662049**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:12:26

**US3662049**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:12:26

**US3662049**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:12:26



**US3662049**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:12:26

**US3662049**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Mar 2008'	System	12 Sep 2020 16:12:26

**US3662049**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2008'	System	12 Sep 2020 16:12:26

**US3662049**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:12:26

**US3662049**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:12:26

US3662049

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Lipodystrophies, PT: Lipodystrophy acquired, LLT: Lipodystrophy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 16:13:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:13:54
Data point term sent to Coder	System	12 Sep 2020 16:13:37
User entered 'Lipodystrophy'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:12:50

**US3662049**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '06 Feb 2002'	Brenda Miller (b) (4)	12 Sep 2020 16:12:50

**US3662049**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:12:50



**US3662049**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:12:50

**US3662049**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:12:50

**US3662049**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:12:50

**US3662049**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Feb 2002'	System	12 Sep 2020 16:12:50

**US3662049**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2002'	System	12 Sep 2020 16:12:50

**US3662049**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:12:50

**US3662049**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:12:50

US3662049

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Bilateral inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 14:10:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 14:10:27
User closed query 'Per MM, please review and amend the term 'INGUINAL HERNIA WITHOUT OBSTRUCTION/ GANGRNE' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 17:34:55
Data point term sent to Coder	System	06 Oct 2020 00:57:52
Query 'Per MM, please review and amend the term 'INGUINAL HERNIA WITHOUT OBSTRUCTION/ GANGRNE' answered with 'updated' (Site from DM).	michelle saemann (b) (4)	06 Oct 2020 00:57:29
User entered 'INGUINAL HERNIA WITHOUT OBSTRUCTION/GANGRENE, BILATeral' reason for change: Data Entry Error	michelle saemann (b) (4)	06 Oct 2020 00:57:22
User entered 'INGUINAL HERNIA WITHOUT OBSTRUCTION/GANGRENe, BILAT' reason for change: Data Entry Error	michelle saemann (b) (4)	06 Oct 2020 00:57:11
Data point term sent to Coder	System	06 Oct 2020 00:56:51
Coding entries removed.	michelle saemann (b) (4)	06 Oct 2020 00:56:34
User entered 'INGuinal HERNIA WITHOUT OBSTRUCTION/GANGREN BILAT' reason for change: Data Entry Error	michelle saemann (b) (4)	06 Oct 2020 00:56:34
User opened query 'Per MM, please review and amend the term 'INGUINAL HERNIA WITHOUT OBSTRUCTION/ GANGRNE' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:16:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Bilateral inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 11:15:42



US3662049

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	13 Sep 2020 11:15:42
User entered 'Ing Hernia Without Obstruction/Gangren Bilat'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:14:46 12 Sep 2020 16:13:59

**US3662049**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '04 Oct 2000'	Brenda Miller (b) (4)	12 Sep 2020 16:13:59

**US3662049**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:13:59

**US3662049**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:13:59

**US3662049**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:13:59

**US3662049**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:13:59

**US3662049**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Oct 2000'	System	12 Sep 2020 16:13:59

**US3662049**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2000'	System	12 Sep 2020 16:13:59



**US3662049**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:13:59

**US3662049**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:13:59

US3662049

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Essential hypertension, LLT: Unspecified essential hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:15:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:15:39
Data point term sent to Coder	System	12 Sep 2020 16:14:46
User entered 'Unspecified Essential Hypertension'	Brenda Miller (b) (4)	12 Sep 2020 16:14:43

**US3662049**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '04 Oct 2000'	Brenda Miller (b) (4)	12 Sep 2020 16:14:43

**US3662049**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:14:43

**US3662049**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:14:43

**US3662049**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:14:43

**US3662049**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:14:43



**US3662049**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Oct 2000'	System	12 Sep 2020 16:14:43

**US3662049**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '2000'	System	12 Sep 2020 16:14:43

**US3662049**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:14:43

**US3662049**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:14:43

US3662049

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:38:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:38:04
Data point term sent to Coder	System	16 Oct 2020 20:18:23
Coding entries removed.	michelle saemann (b) (4)	16 Oct 2020 20:18:01
User entered 'hypogonadism' reason for change: Data Entry Error	michelle saemann (b) (4)	16 Oct 2020 20:18:01
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Male gonadal function disorders, PT: Testicular failure, LLT: Hypofunction testicle - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:16:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:16:40
Data point term sent to Coder	System	12 Sep 2020 16:15:51
User entered 'Other Testicular Hypofunction'	Brenda Miller (b) (4)	12 Sep 2020 16:15:10

**US3662049**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '20 Oct 1999'	Brenda Miller (b) (4)	12 Sep 2020 16:15:10

**US3662049**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:15:10

**US3662049**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:15:10



**US3662049**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:15:10

**US3662049**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:15:10

**US3662049**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Oct 1999'	System	12 Sep 2020 16:15:10

**US3662049**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '1999'	System	12 Sep 2020 16:15:10

**US3662049**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:15:10

**US3662049**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:15:10

US3662049

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depressive disorder - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 20:44:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 20:44:42
Data point term sent to Coder	System	12 Sep 2020 16:15:49
User entered 'Depressive Disorder NEC'	Brenda Miller (b) (4)	12 Sep 2020 16:15:45

**US3662049**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '01 Jul 1999'	Brenda Miller (b) (4)	12 Sep 2020 16:15:45



**US3662049**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:15:45

**US3662049**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:15:45

**US3662049**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:15:45

**US3662049**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:15:45

**US3662049**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Jul 1999'	System	12 Sep 2020 16:15:45

**US3662049**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '1999'	System	12 Sep 2020 16:15:45

**US3662049**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:15:45

**US3662049**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:15:45



US3662049

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:17:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:17:40
Data point term sent to Coder	System	12 Sep 2020 16:16:51
User entered 'Other and Unspecified Hyperlipidemia'	Brenda Miller (b) (4)	12 Sep 2020 16:16:23

**US3662049**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '10 Feb 1999'	Brenda Miller (b) (4)	12 Sep 2020 16:16:23

**US3662049**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:16:23

**US3662049**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:16:23

**US3662049**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:16:23

**US3662049**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:16:23

**US3662049**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Feb 1999'	System	12 Sep 2020 16:16:23

**US3662049**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '1999'	System	12 Sep 2020 16:16:23



**US3662049**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:16:23

**US3662049**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:16:23

US3662049

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: Human immunodeficiency virus syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 16:18:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:18:40
Data point term sent to Coder	System	12 Sep 2020 16:17:53
User entered 'Human Immunodeficiency Virus'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:16:56

**US3662049**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '18 Jun 1996'	Brenda Miller (b) (4)	12 Sep 2020 16:16:56

**US3662049**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:16:56

**US3662049**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:16:56

**US3662049**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:22:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:16:56

**US3662049**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:16:56



**US3662049**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'Jun 1996'	System	12 Sep 2020 16:16:56

**US3662049**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:22:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '1996'	System	12 Sep 2020 16:16:56

**US3662049**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:16:56

**US3662049**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:22:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	12 Sep 2020 16:16:56

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '03 Sep 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '14:10'	Brenda Miller (b) (4)	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '03 Sep 2020 14:10'	System	12 Sep 2020 16:18:51



**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '164.5' cm	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:18:51
DataPoint set to visible.	(b) (4) System	03 Sep 2020 19:00:26

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '83.1' kg	Brenda Miller (b) (4)	12 Sep 2020 16:18:51
DataPoint set to visible.	System	03 Sep 2020 19:00:26

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '30.70925'	System	12 Sep 2020 16:18:51
DataPoint set to visible.	System	03 Sep 2020 19:00:26

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'kg/m2'	System	12 Sep 2020 16:18:51
DataPoint set to visible.	System	03 Sep 2020 19:00:26

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:18:51



**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'bpm'	System	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'breaths/min'	System	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'mmHg'	System	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'mmHg'	System	12 Sep 2020 16:18:51

**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13



**US3662049**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13

**US3662049**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:19:42

**US3662049**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '03 Sep 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:19:42

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

US3662049

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:50

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

US3662049

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:50

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

**Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57



US3662049

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:50

[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 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

US3662049

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:50

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

US3662049

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:50

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

US3662049

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:50

**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 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:20:57



**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

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**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'I'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

US3662049

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

US3662049

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:20:57

**US3662049**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:20:57



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:23:17

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '03 Sep 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:23:17

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	12 Sep 2020 16:23:17

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'VISIT1'	System	12 Sep 2020 16:23:17

US3662049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:44:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:50**

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '188608'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:44:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:50**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:44:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:50**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:23:42



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:50**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:23:42

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:50**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:23:42

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:50**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:23:42

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:50**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:23:42

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:50**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	22 Sep 2020 19:22:55
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:15:31
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:15:30

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:22:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:22:50**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:22:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:25:55



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:22:50**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '03 Sep 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '14:10'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '03 Sep 2020 14:10'	System	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '97.4' F	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Other (Other)'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'INFRARED THERMOMETER'	(b) (4)	
reason for change: Data Entry Error	Brenda Miller (b) (4)	23 Sep 2020 23:37:22
User entered 'TEMPORAL'	(b) (4)	
	Brenda Miller (b) (4)	12 Sep 2020 16:25:55
	(b) (4)	

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '87'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'bpm'	System	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '20'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'breaths/min'	System	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '124'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '82'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:22:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:22:50**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '03 Sep 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

US3662049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User closed query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 15:43, but time of Assessment is 16:12 (29 minutes after). Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 10:05:31
Query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 15:43, but time of Assessment is 16:12 (29 minutes after). Please review and update or provide a clarification. Thank you' answered with 'Correct as entered. Site error by taking vitals 1 minute early' (Site from DM).	michelle saemann (b) (4) (b) (4)	21 Sep 2020 19:00:32
User opened query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 15:43, but time of Assessment is 16:12 (29 minutes after). Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:00:58
User entered '16:12'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '03 Sep 2020 16:12'	System	12 Sep 2020 16:25:55



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '97.1' F	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Other (Other)'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'INFRARED THERMOMETER'	(b) (4)	
reason for change: Data Entry Error	Brenda Miller (b) (4)	23 Sep 2020 23:37:22
User entered 'TEMPORAL'	(b) (4)	
	Brenda Miller (b) (4)	12 Sep 2020 16:25:55
	(b) (4)	

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '77'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'bpm'	System	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '16'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'breaths/min'	System	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '140'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '84'	Brenda Miller (b) (4)	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	12 Sep 2020 16:25:55

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:26:08

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:26:08

US3662049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User closed query 'Per CDM: Please complete Visit date ,Vitals Signs - Dosing, PE ,Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab , Continuing forms for Visit1 Day1 as pages 15-16 per CCGs. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 10:47:23
Query 'Per CDM: Please complete Visit date ,Vitals Signs - Dosing, PE ,Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab , Continuing forms for Visit1 Day1 as pages 15-16 per CCGs. Thank you.' answered with 'All required forms completed' (Site from DM).	Brenda Miller (b) (4) (b) (4)	14 Sep 2020 14:05:52
User opened query 'Per CDM: Please complete Visit date ,Vitals Signs - Dosing, PE ,Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab , Continuing forms for Visit1 Day1 as pages 15-16 per CCGs. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:36:53
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	03 Sep 2020 19:47:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:47:38

US3662049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:47:38



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '3 Sep 2020'	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:47:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '15:43'	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:47:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '3 Sep 2020 15:43'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) michelle saemann (b) (4)	03 Sep 2020 19:47:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'ONCE'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:26:48



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '03 Sep 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:26:48

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '14:50'	Brenda Miller (b) (4)	12 Sep 2020 16:26:48

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '03 Sep 2020 14:50'	System	12 Sep 2020 16:26:48

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:22:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '03 Sep 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:27:13

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:27:13

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:27:13

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '14:45'	Brenda Miller (b) (4)	12 Sep 2020 16:27:13

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '03 Sep 2020 14:45'	System	12 Sep 2020 16:27:13



**US3662049**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:27:13

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:27:13

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:27:13

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered empty.	System	12 Sep 2020 16:27:13

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:27:27

**US3662049**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'I'	System	12 Sep 2020 16:27:27

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:59', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '31a7700b-7015-4684-8fc2-3965dfc07636'	System	03 Sep 2020 20:16:25
User entered 'Yes (Y)'	System	03 Sep 2020 20:16:25



US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:16:08', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '31a7700b-7015-4684-8fc2-3965dfc07636' User entered '97.1'	System	03 Sep 2020 20:16:25
	System	03 Sep 2020 20:16:25

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:16:18', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '31a7700b-7015-4684-8fc2-3965dfc07636'	System	03 Sep 2020 20:16:25
User entered 'No (N)'	System	03 Sep 2020 20:16:25

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:16:22', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '31a7700b-7015-4684-8fc2-3965dfc07636'	System	03 Sep 2020 20:16:25
User entered '03 Sep 2020 16:16'	System	03 Sep 2020 20:16:25

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Sep 2020 16:03'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Sep 2020 18:33'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:52:29', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5a8b2ee0-3225-4fc6-8aec-22b10c9445b2'	System	03 Sep 2020 23:52:49
User entered 'Yes (Y)'	System	03 Sep 2020 23:52:49

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:52:37', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5a8b2ee0-3225-4fc6-8aec-22b10c9445b2'	System	03 Sep 2020 23:52:49
User entered '97.1'	System	03 Sep 2020 23:52:49



US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:52:42', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5a8b2ee0-3225-4fc6-8aec-22b10c9445b2'	System	03 Sep 2020 23:52:49
User entered 'No (N)'	System	03 Sep 2020 23:52:49

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:52:47', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5a8b2ee0-3225-4fc6-8aec-22b10c9445b2'	System	03 Sep 2020 23:52:49
User entered '03 Sep 2020 19:52'	System	03 Sep 2020 23:52:49

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Sep 2020 19:28'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 2'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:55:20', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'fcbc1e72-0632-438c-b831-b24fd450e6b8'	System	04 Sep 2020 20:55:42
User entered 'Yes (Y)'	System	04 Sep 2020 20:55:42

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:55:29', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'fcbc1e72-0632-438c-b831-b24fd450e6b8'	System	04 Sep 2020 20:55:42
User entered '97.6'	System	04 Sep 2020 20:55:42

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:55:34', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'fcbc1e72-0632-438c-b831-b24fd450e6b8'	System	04 Sep 2020 20:55:42
User entered 'No (N)'	System	04 Sep 2020 20:55:42



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:55:39', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'fcbc1e72-0632-438c-b831-b24fd450e6b8'	System	04 Sep 2020 20:55:42
User entered '04 Sep 2020 16:55'	System	04 Sep 2020 20:55:42

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 3'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:05:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '29ae4b6c-e8b9-49a9-9d77-191aabec5ef5'	System	05 Sep 2020 23:06:19
User entered 'Yes (Y)'	System	05 Sep 2020 23:06:19

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:01', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '29ae4b6c-e8b9-49a9-9d77-191aabec5ef5'	System	05 Sep 2020 23:06:19
User entered '97.8'	System	05 Sep 2020 23:06:19

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:05', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '29ae4b6c-e8b9-49a9-9d77-191aabec5ef5'	System	05 Sep 2020 23:06:19
User entered 'No (N)'	System	05 Sep 2020 23:06:19

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:16', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '29ae4b6c-e8b9-49a9-9d77-191aabec5ef5'	System	05 Sep 2020 23:06:19
User entered '05 Sep 2020 19:06'	System	05 Sep 2020 23:06:19



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 4'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:07:39', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'dfe0a79d-8494-43fc-8f42-eb39994f9237'	System	06 Sep 2020 20:08:01
User entered 'Yes (Y)'	System	06 Sep 2020 20:08:01

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:07:47', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'dfe0a79d-8494-43fc-8f42-eb39994f9237'	System	06 Sep 2020 20:08:01
User entered '97.8'	System	06 Sep 2020 20:08:01

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:07:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'dfe0a79d-8494-43fc-8f42-eb39994f9237'	System	06 Sep 2020 20:08:01
User entered 'No (N)'	System	06 Sep 2020 20:08:01

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:07:57', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'dfe0a79d-8494-43fc-8f42-eb39994f9237'	System	06 Sep 2020 20:08:01
User entered '06 Sep 2020 16:07'	System	06 Sep 2020 20:08:01

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:47:38



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 5'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:15', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '58fa865c-3ad0-4902-91b5-c2a97421eca5'	System	07 Sep 2020 19:49:34
User entered 'Yes (Y)'	System	07 Sep 2020 19:49:34

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:20', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '58fa865c-3ad0-4902-91b5-c2a97421eca5'	System	07 Sep 2020 19:49:34
User entered '97.8'	System	07 Sep 2020 19:49:34

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:24', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '58fa865c-3ad0-4902-91b5-c2a97421eca5'	System	07 Sep 2020 19:49:34
User entered 'No (N)'	System	07 Sep 2020 19:49:34

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:28', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '58fa865c-3ad0-4902-91b5-c2a97421eca5'	System	07 Sep 2020 19:49:34
User entered '07 Sep 2020 15:49'	System	07 Sep 2020 19:49:34

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:47:38



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 6'	System	03 Sep 2020 19:47:38

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:55:32', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ab93da3a-32f8-48b2-a8f3-678e7c75b5f7'	System	08 Sep 2020 22:55:49
User entered 'Yes (Y)'	System	08 Sep 2020 22:55:49

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:55:37', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ab93da3a-32f8-48b2-a8f3-678e7c75b5f7'	System	08 Sep 2020 22:55:49
User entered '97.8'	System	08 Sep 2020 22:55:49

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:55:42', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ab93da3a-32f8-48b2-a8f3-678e7c75b5f7'	System	08 Sep 2020 22:55:49
User entered 'No (N)'	System	08 Sep 2020 22:55:49

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:55:45', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ab93da3a-32f8-48b2-a8f3-678e7c75b5f7'	System	08 Sep 2020 22:55:49
User entered '08 Sep 2020 18:55'	System	08 Sep 2020 22:55:49

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 7'	System	03 Sep 2020 19:47:38



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:45:36', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'd3801d13-0dc0-4bcb-996f-41b706d6f6a1'	System	09 Sep 2020 20:45:53
User entered 'Yes (Y)'	System	09 Sep 2020 20:45:53

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:45:42', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'd3801d13-0dc0-4bcb-996f-41b706d6f6a1'	System	09 Sep 2020 20:45:53
User entered '97.6'	System	09 Sep 2020 20:45:53

US3662049

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:45:45', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'd3801d13-0dc0-4bcb-996f-41b706d6f6a1'	System	09 Sep 2020 20:45:53
User entered 'No (N)'	System	09 Sep 2020 20:45:53

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:45:49', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'd3801d13-0dc0-4bcb-996f-41b706d6f6a1'	System	09 Sep 2020 20:45:53
User entered '09 Sep 2020 16:45'	System	09 Sep 2020 20:45:53

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:47:38

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:14:24', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ac38754d-1530-47bd-b67e-a1c7062f577a'	System	03 Sep 2020 20:15:06
User entered 'None (1)'	System	03 Sep 2020 20:15:06



US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:14:41', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ac38754d-1530-47bd-b67e-a1c7062f577a'	System	03 Sep 2020 20:15:06
User entered 'No (N)'	System	03 Sep 2020 20:15:06

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:14:45', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ac38754d-1530-47bd-b67e-a1c7062f577a'	System	03 Sep 2020 20:15:06
User entered 'No (N)'	System	03 Sep 2020 20:15:06

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:14:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ac38754d-1530-47bd-b67e-a1c7062f577a'	System	03 Sep 2020 20:15:06
User entered 'None (1)'	System	03 Sep 2020 20:15:06

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:03', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ac38754d-1530-47bd-b67e-a1c7062f577a'	System	03 Sep 2020 20:15:06
User entered '03 Sep 2020 16:15'	System	03 Sep 2020 20:15:06

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Sep 2020 16:03'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Sep 2020 18:33'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:47:38

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:52:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e8c2c5-a72c-4f69-9e8a-2bc458053761'	System	03 Sep 2020 23:53:11
User entered 'None (1)'	System	03 Sep 2020 23:53:11



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:52:57', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e8c2c5-a72c-4f69-9e8a-2bc458053761'	System	03 Sep 2020 23:53:11
User entered 'No (N)'	System	03 Sep 2020 23:53:11

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e8c2c5-a72c-4f69-9e8a-2bc458053761'	System	03 Sep 2020 23:53:11
User entered 'No (N)'	System	03 Sep 2020 23:53:11

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:05', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e8c2c5-a72c-4f69-9e8a-2bc458053761'	System	03 Sep 2020 23:53:11
User entered 'None (1)'	System	03 Sep 2020 23:53:11

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:09', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e8c2c5-a72c-4f69-9e8a-2bc458053761'	System	03 Sep 2020 23:53:11
User entered '03 Sep 2020 19:53'	System	03 Sep 2020 23:53:11

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Sep 2020 19:28'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 2'	System	03 Sep 2020 19:47:38

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:55:46', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '935bba97-b38e-46fe-83a2-242773aa4009'	System	04 Sep 2020 20:56:06
User entered 'None (1)'	System	04 Sep 2020 20:56:06



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:55:49', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '935bba97-b38e-46fe-83a2-242773aa4009'	System	04 Sep 2020 20:56:06
User entered 'No (N)'	System	04 Sep 2020 20:56:06

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:55:52', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '935bba97-b38e-46fe-83a2-242773aa4009'	System	04 Sep 2020 20:56:06
User entered 'No (N)'	System	04 Sep 2020 20:56:06

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:55:59', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '935bba97-b38e-46fe-83a2-242773aa4009'	System	04 Sep 2020 20:56:06
User entered 'None (1)'	System	04 Sep 2020 20:56:06

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:56:02', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '935bba97-b38e-46fe-83a2-242773aa4009'	System	04 Sep 2020 20:56:06
User entered '04 Sep 2020 16:56'	System	04 Sep 2020 20:56:06

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 3'	System	03 Sep 2020 19:47:38

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:30', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52ac61bd-41e2-4dc9-b0ac-626b3623448d'	System	05 Sep 2020 23:06:45
User entered 'None (1)'	System	05 Sep 2020 23:06:45



US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:27', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52ac61bd-41e2-4dc9-b0ac-626b3623448d'	System	05 Sep 2020 23:06:45
User entered 'No (N)'	System	05 Sep 2020 23:06:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:33', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52ac61bd-41e2-4dc9-b0ac-626b3623448d'	System	05 Sep 2020 23:06:45
User entered 'No (N)'	System	05 Sep 2020 23:06:45

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:37', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52ac61bd-41e2-4dc9-b0ac-626b3623448d'	System	05 Sep 2020 23:06:45
User entered 'None (1)'	System	05 Sep 2020 23:06:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:43', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52ac61bd-41e2-4dc9-b0ac-626b3623448d'	System	05 Sep 2020 23:06:45
User entered '05 Sep 2020 19:06'	System	05 Sep 2020 23:06:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 4'	System	03 Sep 2020 19:47:38

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:06', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ad5b0fb0-8e27-4f1e-8e0b-e4fff6675f57'	System	06 Sep 2020 20:08:24
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 20:08:24



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:09', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ad5b0fb0-8e27-4f1e-8e0b-e4fff6675f57'	System	06 Sep 2020 20:08:24
User entered 'No (N)'	System	06 Sep 2020 20:08:24

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:14', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ad5b0fb0-8e27-4f1e-8e0b-e4fff6675f57'	System	06 Sep 2020 20:08:24
User entered 'No (N)'	System	06 Sep 2020 20:08:24

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:18', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ad5b0fb0-8e27-4f1e-8e0b-e4fff6675f57'	System	06 Sep 2020 20:08:24
User entered 'None (1)'	System	06 Sep 2020 20:08:24

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:22', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ad5b0fb0-8e27-4f1e-8e0b-e4fff6675f57'	System	06 Sep 2020 20:08:24
User entered '06 Sep 2020 16:08'	System	06 Sep 2020 20:08:24

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 5'	System	03 Sep 2020 19:47:38

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:34', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7f72a311-d9fa-4879-b209-f8bdd0096398'	System	07 Sep 2020 19:49:51
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 19:49:51



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:36', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7f72a311-d9fa-4879-b209-f8bdd0096398'	System	07 Sep 2020 19:49:51
User entered 'No (N)'	System	07 Sep 2020 19:49:51

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:39', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7f72a311-d9fa-4879-b209-f8bdd0096398'	System	07 Sep 2020 19:49:51
User entered 'No (N)'	System	07 Sep 2020 19:49:51

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:44', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7f72a311-d9fa-4879-b209-f8bdd0096398'	System	07 Sep 2020 19:49:51
User entered 'None (1)'	System	07 Sep 2020 19:49:51

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:47', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7f72a311-d9fa-4879-b209-f8bdd0096398'	System	07 Sep 2020 19:49:51
User entered '07 Sep 2020 15:49'	System	07 Sep 2020 19:49:51

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 6'	System	03 Sep 2020 19:47:38

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:55:52', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1d402306-89a8-4077-b796-853c8671ca97'	System	08 Sep 2020 22:56:07
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 22:56:07



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:55:55', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1d402306-89a8-4077-b796-853c8671ca97'	System	08 Sep 2020 22:56:07
User entered 'No (N)'	System	08 Sep 2020 22:56:07

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:55:58', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1d402306-89a8-4077-b796-853c8671ca97'	System	08 Sep 2020 22:56:07
User entered 'No (N)'	System	08 Sep 2020 22:56:07

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:01', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1d402306-89a8-4077-b796-853c8671ca97'	System	08 Sep 2020 22:56:07
User entered 'None (1)'	System	08 Sep 2020 22:56:07

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:04', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1d402306-89a8-4077-b796-853c8671ca97'	System	08 Sep 2020 22:56:07
User entered '08 Sep 2020 18:56'	System	08 Sep 2020 22:56:07

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 7'	System	03 Sep 2020 19:47:38

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:45:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf49842-9d9f-4fb0-a403-183f286c2ea1'	System	09 Sep 2020 20:46:11
User entered 'None (1)'	System	09 Sep 2020 20:46:11



US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:45:57', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf49842-9d9f-4fb0-a403-183f286c2ea1'	System	09 Sep 2020 20:46:11
User entered 'No (N)'	System	09 Sep 2020 20:46:11

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:01', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf49842-9d9f-4fb0-a403-183f286c2ea1'	System	09 Sep 2020 20:46:11
User entered 'No (N)'	System	09 Sep 2020 20:46:11

US3662049

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:04', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf49842-9d9f-4fb0-a403-183f286c2ea1'	System	09 Sep 2020 20:46:11
User entered 'None (1)'	System	09 Sep 2020 20:46:11

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:06', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf49842-9d9f-4fb0-a403-183f286c2ea1'	System	09 Sep 2020 20:46:11
User entered '09 Sep 2020 16:46'	System	09 Sep 2020 20:46:11

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:10', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f1422230-91ea-42a0-9b46-fa14d13f591e'	System	03 Sep 2020 20:15:37
User entered 'None (0)'	System	03 Sep 2020 20:15:37



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:13', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f1422230-91ea-42a0-9b46-fa14d13f591e'	System	03 Sep 2020 20:15:37
User entered 'None (0)'	System	03 Sep 2020 20:15:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:15', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f1422230-91ea-42a0-9b46-fa14d13f591e'	System	03 Sep 2020 20:15:37
User entered 'None (0)'	System	03 Sep 2020 20:15:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:19', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f1422230-91ea-42a0-9b46-fa14d13f591e'	System	03 Sep 2020 20:15:37
User entered 'None (0)'	System	03 Sep 2020 20:15:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:21', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f1422230-91ea-42a0-9b46-fa14d13f591e'	System	03 Sep 2020 20:15:37
User entered 'None (0)'	System	03 Sep 2020 20:15:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:24', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f1422230-91ea-42a0-9b46-fa14d13f591e'	System	03 Sep 2020 20:15:37
User entered 'None (0)'	System	03 Sep 2020 20:15:37

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:29', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f1422230-91ea-42a0-9b46-fa14d13f591e'	System	03 Sep 2020 20:15:37
User entered 'No (N)'	System	03 Sep 2020 20:15:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T16:15:34', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f1422230-91ea-42a0-9b46-fa14d13f591e'	System	03 Sep 2020 20:15:37
User entered '03 Sep 2020 16:15'	System	03 Sep 2020 20:15:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Sep 2020 16:03'	System	03 Sep 2020 19:47:38



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Sep 2020 18:33'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:17', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '85cef6ce-77e4-4e12-9987-8a19dca27a70'	System	03 Sep 2020 23:53:45
User entered 'None (0)'	System	03 Sep 2020 23:53:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:20', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '85cef6ce-77e4-4e12-9987-8a19dca27a70'	System	03 Sep 2020 23:53:45
User entered 'None (0)'	System	03 Sep 2020 23:53:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:23', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '85cef6ce-77e4-4e12-9987-8a19dca27a70'	System	03 Sep 2020 23:53:45
User entered 'None (0)'	System	03 Sep 2020 23:53:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:26', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '85cef6ce-77e4-4e12-9987-8a19dca27a70'	System	03 Sep 2020 23:53:45
User entered 'None (0)'	System	03 Sep 2020 23:53:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:29', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '85cef6ce-77e4-4e12-9987-8a19dca27a70'	System	03 Sep 2020 23:53:45
User entered 'None (0)'	System	03 Sep 2020 23:53:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:33', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '85cef6ce-77e4-4e12-9987-8a19dca27a70'	System	03 Sep 2020 23:53:45
User entered 'None (0)'	System	03 Sep 2020 23:53:45



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:38', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '85cef6ce-77e4-4e12-9987-8a19dca27a70'	System	03 Sep 2020 23:53:45
User entered 'No (N)'	System	03 Sep 2020 23:53:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-03T19:53:42', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '85cef6ce-77e4-4e12-9987-8a19dca27a70'	System	03 Sep 2020 23:53:45
User entered '03 Sep 2020 19:53'	System	03 Sep 2020 23:53:45

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Sep 2020 19:28'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 2'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:56:08', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e5ae51-8d05-4a07-bdfa-bba480c6751f'	System	04 Sep 2020 20:56:41
User entered 'None (0)'	System	04 Sep 2020 20:56:41

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:56:10', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e5ae51-8d05-4a07-bdfa-bba480c6751f' User entered 'None (0)'	System	04 Sep 2020 20:56:41
	System	04 Sep 2020 20:56:41

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:56:14', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e5ae51-8d05-4a07-bdfa-bba480c6751f'	System	04 Sep 2020 20:56:41
User entered 'None (0)'	System	04 Sep 2020 20:56:41



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:56:16', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e5ae51-8d05-4a07-bdfa-bba480c6751f' User entered 'None (0)'	System	04 Sep 2020 20:56:41
	System	04 Sep 2020 20:56:41

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:56:19', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e5ae51-8d05-4a07-bdfa-bba480c6751f' User entered 'None (0)'	System	04 Sep 2020 20:56:41
	System	04 Sep 2020 20:56:41

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:56:22', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e5ae51-8d05-4a07-bdfa-bba480c6751f'	System	04 Sep 2020 20:56:41
User entered 'None (0)'	System	04 Sep 2020 20:56:41

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:56:27', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e5ae51-8d05-4a07-bdfa-bba480c6751f'	System	04 Sep 2020 20:56:41
User entered 'No (N)'	System	04 Sep 2020 20:56:41

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-04T16:56:36', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '75e5ae51-8d05-4a07-bdfa-bba480c6751f'	System	04 Sep 2020 20:56:41
User entered '04 Sep 2020 16:56'	System	04 Sep 2020 20:56:41

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 3'	System	03 Sep 2020 19:47:38



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:48', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0707f86b-bc74-4439-997f-8288c3702645'	System	05 Sep 2020 23:07:21
User entered 'None (0)'	System	05 Sep 2020 23:07:21

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0707f86b-bc74-4439-997f-8288c3702645'	System	05 Sep 2020 23:07:21
User entered 'None (0)'	System	05 Sep 2020 23:07:21

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0707f86b-bc74-4439-997f-8288c3702645'	System	05 Sep 2020 23:07:21
User entered 'None (0)'	System	05 Sep 2020 23:07:21

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:06:57', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0707f86b-bc74-4439-997f-8288c3702645'	System	05 Sep 2020 23:07:21
User entered 'None (0)'	System	05 Sep 2020 23:07:21

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:07:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0707f86b-bc74-4439-997f-8288c3702645'	System	05 Sep 2020 23:07:21
User entered 'None (0)'	System	05 Sep 2020 23:07:21

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:07:02', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0707f86b-bc74-4439-997f-8288c3702645'	System	05 Sep 2020 23:07:21
User entered 'None (0)'	System	05 Sep 2020 23:07:21

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:50

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:07:10', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0707f86b-bc74-4439-997f-8288c3702645'	System	05 Sep 2020 23:07:21
User entered 'No (N)'	System	05 Sep 2020 23:07:21

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-05T19:07:17', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0707f86b-bc74-4439-997f-8288c3702645'	System	05 Sep 2020 23:07:21
User entered '05 Sep 2020 19:07'	System	05 Sep 2020 23:07:21



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 4'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:26', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '3cf60249-818f-41e6-a2b4-fb68f0f5a02a'	System	06 Sep 2020 20:08:54
User entered 'None (0)'	System	06 Sep 2020 20:08:54

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:29', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '3cf60249-818f-41e6-a2b4-fb68f0f5a02a'	System	06 Sep 2020 20:08:54
User entered 'None (0)'	System	06 Sep 2020 20:08:54

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:32', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '3cf60249-818f-41e6-a2b4-fb68f0f5a02a' User entered 'None (0)'	System	06 Sep 2020 20:08:54
	System	06 Sep 2020 20:08:54

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:35', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '3cf60249-818f-41e6-a2b4-fb68f0f5a02a'	System	06 Sep 2020 20:08:54
User entered 'None (0)'	System	06 Sep 2020 20:08:54

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:38', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '3cf60249-818f-41e6-a2b4-fb68f0f5a02a'	System	06 Sep 2020 20:08:54
User entered 'None (0)'	System	06 Sep 2020 20:08:54



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:41', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '3cf60249-818f-41e6-a2b4-fb68f0f5a02a'	System	06 Sep 2020 20:08:54
User entered 'None (0)'	System	06 Sep 2020 20:08:54

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:44', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '3cf60249-818f-41e6-a2b4-fb68f0f5a02a'	System	06 Sep 2020 20:08:54
User entered 'No (N)'	System	06 Sep 2020 20:08:54

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-06T16:08:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '3cf60249-818f-41e6-a2b4-fb68f0f5a02a'	System	06 Sep 2020 20:08:54
User entered '06 Sep 2020 16:08'	System	06 Sep 2020 20:08:54

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 5'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:49:59', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2e7c6083-7994-4b60-94ff-f1abb0d91667'	System	07 Sep 2020 19:50:28
User entered 'None (0)'	System	07 Sep 2020 19:50:28

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:50:02', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2e7c6083-7994-4b60-94ff-f1abb0d91667'	System	07 Sep 2020 19:50:28
User entered 'None (0)'	System	07 Sep 2020 19:50:28



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:50:05', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2e7c6083-7994-4b60-94ff-f1abb0d91667'	System	07 Sep 2020 19:50:28
User entered 'None (0)'	System	07 Sep 2020 19:50:28

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:50:08', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2e7c6083-7994-4b60-94ff-f1abb0d91667'	System	07 Sep 2020 19:50:28
User entered 'None (0)'	System	07 Sep 2020 19:50:28

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:50:11', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2e7c6083-7994-4b60-94ff-f1abb0d91667'	System	07 Sep 2020 19:50:28
User entered 'None (0)'	System	07 Sep 2020 19:50:28

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:50:13', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2e7c6083-7994-4b60-94ff-f1abb0d91667'	System	07 Sep 2020 19:50:28
User entered 'None (0)'	System	07 Sep 2020 19:50:28

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:50:17', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2e7c6083-7994-4b60-94ff-f1abb0d91667'	System	07 Sep 2020 19:50:28
User entered 'No (N)'	System	07 Sep 2020 19:50:28

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-07T15:50:24', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2e7c6083-7994-4b60-94ff-f1abb0d91667'	System	07 Sep 2020 19:50:28
User entered '07 Sep 2020 15:50'	System	07 Sep 2020 19:50:28

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:47:38



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 6'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:09', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7caf44e9-31ce-4022-af8a-666e3c45094a'	System	08 Sep 2020 22:56:36
User entered 'None (0)'	System	08 Sep 2020 22:56:36

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:11', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7caf44e9-31ce-4022-af8a-666e3c45094a'	System	08 Sep 2020 22:56:36
User entered 'None (0)'	System	08 Sep 2020 22:56:36

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:14', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7caf44e9-31ce-4022-af8a-666e3c45094a'	System	08 Sep 2020 22:56:36
User entered 'None (0)'	System	08 Sep 2020 22:56:36

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:18', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7caf44e9-31ce-4022-af8a-666e3c45094a'	System	08 Sep 2020 22:56:36
User entered 'None (0)'	System	08 Sep 2020 22:56:36

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:21', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7caf44e9-31ce-4022-af8a-666e3c45094a'	System	08 Sep 2020 22:56:36
User entered 'None (0)'	System	08 Sep 2020 22:56:36

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:23', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7caf44e9-31ce-4022-af8a-666e3c45094a'	System	08 Sep 2020 22:56:36
User entered 'None (0)'	System	08 Sep 2020 22:56:36

US3662049

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:50

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:28', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7caf44e9-31ce-4022-af8a-666e3c45094a'	System	08 Sep 2020 22:56:36
User entered 'No (N)'	System	08 Sep 2020 22:56:36



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-08T18:56:33', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '7caf44e9-31ce-4022-af8a-666e3c45094a'	System	08 Sep 2020 22:56:36
User entered '08 Sep 2020 18:56'	System	08 Sep 2020 22:56:36

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 7'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:10', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cf3fdb0a-82ee-46ed-9c2e-179067ea0ec3'	System	09 Sep 2020 20:46:37
User entered 'None (0)'	System	09 Sep 2020 20:46:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:13', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cf3fdb0a-82ee-46ed-9c2e-179067ea0ec3'	System	09 Sep 2020 20:46:37
User entered 'None (0)'	System	09 Sep 2020 20:46:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:17', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cf3fdb0a-82ee-46ed-9c2e-179067ea0ec3'	System	09 Sep 2020 20:46:37
User entered 'None (0)'	System	09 Sep 2020 20:46:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:20', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cf3fdb0a-82ee-46ed-9c2e-179067ea0ec3'	System	09 Sep 2020 20:46:37
User entered 'None (0)'	System	09 Sep 2020 20:46:37



**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:22', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cf3fdb0a-82ee-46ed-9c2e-179067ea0ec3'	System	09 Sep 2020 20:46:37
User entered 'None (0)'	System	09 Sep 2020 20:46:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:26', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cf3fdb0a-82ee-46ed-9c2e-179067ea0ec3'	System	09 Sep 2020 20:46:37
User entered 'None (0)'	System	09 Sep 2020 20:46:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:28', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cf3fdb0a-82ee-46ed-9c2e-179067ea0ec3'	System	09 Sep 2020 20:46:37
User entered 'Yes (Y)'	System	09 Sep 2020 20:46:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-09-09T16:46:34', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cf3fdb0a-82ee-46ed-9c2e-179067ea0ec3'	System	09 Sep 2020 20:46:37
User entered '09 Sep 2020 16:46'	System	09 Sep 2020 20:46:37

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:41:51

**US3662049**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '12 Sep 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:41:51



**US3662049**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	12 Sep 2020 16:41:51

**US3662049**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:41:51

**US3662049**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	18 Sep 2020 17:55:01

**US3662049**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'I'	System	18 Sep 2020 17:55:01

**US3662049**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	18 Sep 2020 17:55:36

**US3662049**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '18 Sep 2020'	Brenda Miller (b) (4)	18 Sep 2020 17:55:36

**US3662049**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	18 Sep 2020 17:55:36

**US3662049**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	18 Sep 2020 17:55:36



**US3662049**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 15:32:39

**US3662049**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User entered 'I'	System	25 Sep 2020 15:32:39

**US3662049**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 15:32:59

**US3662049**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '25 Sep 2020'	Brenda Miller (b) (4)	25 Sep 2020 15:32:59

**US3662049**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	25 Sep 2020 15:32:59

**US3662049**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 15:32:59

**US3662049**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	30 Sep 2020 16:56:47

**US3662049**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:14:51
User entered 'I'	System	30 Sep 2020 16:56:47



**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 17:20:21

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '30 Sep 2020'	Brenda Miller (b) (4)	02 Oct 2020 17:20:21

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	02 Oct 2020 17:20:21

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'VISIT2'	System	02 Oct 2020 17:20:21

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '30 Sep 2020'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '11:50'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08



**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '30 Sep 2020 11:50'	System	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '97.2' F	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Other (Other)'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '87'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'bpm'	System	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '16'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'breaths/min'	System	02 Oct 2020 17:22:08



**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '141'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '83'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '30 Sep 2020'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '13:22'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08



**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '30 Sep 2020 13:22'	System	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '97.8' F	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Other (Other)'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '90'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'bpm'	System	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '12'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'breaths/min'	System	02 Oct 2020 17:22:08



**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '126'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '77'	Brenda Miller (b) (4)	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	02 Oct 2020 17:22:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 17:22:28

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '30 Sep 2020'	Brenda Miller (b) (4)	02 Oct 2020 17:22:28

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	30 Sep 2020 16:57:09

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	(b) (4) michelle saemann (b) (4)	30 Sep 2020 16:57:09



**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	(b) (4) michelle saemann (b) (4)	30 Sep 2020 16:57:09

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '30 Sep 2020'	(b) (4) michelle saemann (b) (4)	30 Sep 2020 16:57:09

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '12:49'	(b) (4) michelle saemann (b) (4)	30 Sep 2020 16:57:09

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '30 Sep 2020 12:49'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) michelle saemann (b) (4)	30 Sep 2020 16:57:09

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'ONCE'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:50**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 17:23:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '30 Sep 2020'	Brenda Miller (b) (4)	02 Oct 2020 17:23:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '12:00'	Brenda Miller (b) (4)	02 Oct 2020 17:23:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '30 Sep 2020 12:00'	System	02 Oct 2020 17:23:08

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '30 Sep 2020'	Brenda Miller (b) (4)	02 Oct 2020 17:23:35

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	02 Oct 2020 17:23:35

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 17:23:35

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '11:55'	Brenda Miller (b) (4)	02 Oct 2020 17:23:35



**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '30 Sep 2020 11:55'	System	02 Oct 2020 17:23:35

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	02 Oct 2020 17:23:35

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'No (N)'	Brenda Miller (b) (4)	02 Oct 2020 17:23:35

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Brenda Miller (b) (4)	02 Oct 2020 17:23:35

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered empty.	System	02 Oct 2020 17:23:35

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 17:23:44

**US3662049**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '1'	System	02 Oct 2020 17:23:44

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:25:38', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f4e33c3d-37a0-4b1a-91b4-c3705235f840' User entered 'Yes (Y)'	System	30 Sep 2020 17:25:57
	System	30 Sep 2020 17:25:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:25:46', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f4e33c3d-37a0-4b1a-91b4-c3705235f840' User entered '97.8'	System	30 Sep 2020 17:25:57
	System	30 Sep 2020 17:25:57

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:25:50', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f4e33c3d-37a0-4b1a-91b4-c3705235f840' User entered 'No (N)'	System	30 Sep 2020 17:25:57
	System	30 Sep 2020 17:25:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:25:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f4e33c3d-37a0-4b1a-91b4-c3705235f840' User entered '30 Sep 2020 13:25'	System	30 Sep 2020 17:25:57
	System	30 Sep 2020 17:25:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '30 Sep 2020 13:09'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '30 Sep 2020 15:39'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:07:53', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'c48ef00a-2712-4d0f-b304-ae3ee7b50be5' User entered 'Yes (Y)'	System	30 Sep 2020 23:08:09
	System	30 Sep 2020 23:08:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'c48ef00a-2712-4d0f-b304-ae3ee7b50be5' User entered '97.2'	System	30 Sep 2020 23:08:09
	System	30 Sep 2020 23:08:09

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:03', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'c48ef00a-2712-4d0f-b304-ae3ee7b50be5'	System	30 Sep 2020 23:08:09
User entered 'No (N)'	System	30 Sep 2020 23:08:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:07', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'c48ef00a-2712-4d0f-b304-ae3ee7b50be5' User entered '30 Sep 2020 19:08'	System	30 Sep 2020 23:08:09
	System	30 Sep 2020 23:08:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '30 Sep 2020 16:34'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 2'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:08:44', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1362f00c-9a34-4c08-b07f-c3a18cc2ef63' User entered 'Yes (Y)'	System	01 Oct 2020 22:09:01
	System	01 Oct 2020 22:09:01

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:08:50', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1362f00c-9a34-4c08-b07f-c3a18cc2ef63' User entered '97.8'	System	01 Oct 2020 22:09:01
	System	01 Oct 2020 22:09:01



US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:08:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1362f00c-9a34-4c08-b07f-c3a18cc2ef63' User entered 'No (N)'	System	01 Oct 2020 22:09:01
	System	01 Oct 2020 22:09:01

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:08:59', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1362f00c-9a34-4c08-b07f-c3a18cc2ef63' User entered '01 Oct 2020 18:08'	System	01 Oct 2020 22:09:01
	System	01 Oct 2020 22:09:01

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 3'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:11', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '37c92cd2-721a-4c78-8408-83fe6a4ce30c' User entered 'Yes (Y)'	System	02 Oct 2020 20:47:29
	System	02 Oct 2020 20:47:29

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:17', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '37c92cd2-721a-4c78-8408-83fe6a4ce30c' User entered '97.5'	System	02 Oct 2020 20:47:29
	System	02 Oct 2020 20:47:29

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:20', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '37c92cd2-721a-4c78-8408-83fe6a4ce30c' User entered 'No (N)'	System	02 Oct 2020 20:47:29
	System	02 Oct 2020 20:47:29



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:26', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '37c92cd2-721a-4c78-8408-83fe6a4ce30c' User entered '02 Oct 2020 16:47'	System	02 Oct 2020 20:47:29
	System	02 Oct 2020 20:47:29

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 4'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:47:35', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1468eb93-36e6-4f96-8ec2-53d817d22545' User entered 'Yes (Y)'	System	04 Oct 2020 12:47:52
	System	04 Oct 2020 12:47:52

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:47:41', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1468eb93-36e6-4f96-8ec2-53d817d22545' User entered '97.7'	System	04 Oct 2020 12:47:52
	System	04 Oct 2020 12:47:52

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:47:45', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1468eb93-36e6-4f96-8ec2-53d817d22545' User entered 'No (N)'	System	04 Oct 2020 12:47:52
	System	04 Oct 2020 12:47:52

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:47:49', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1468eb93-36e6-4f96-8ec2-53d817d22545' User entered '04 Oct 2020 08:47'	System	04 Oct 2020 12:47:52
	System	04 Oct 2020 12:47:52



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 5'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:09', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'c23704b9-d6e1-43e1-a8fb-8b9ac391f5e0' User entered 'Yes (Y)'	System	05 Oct 2020 01:20:25
	System	05 Oct 2020 01:20:25

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:15', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'c23704b9-d6e1-43e1-a8fb-8b9ac391f5e0' User entered '97.2'	System	05 Oct 2020 01:20:25
	System	05 Oct 2020 01:20:25

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:19', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'c23704b9-d6e1-43e1-a8fb-8b9ac391f5e0' User entered 'No (N)'	System	05 Oct 2020 01:20:25
	System	05 Oct 2020 01:20:25

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:22', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'c23704b9-d6e1-43e1-a8fb-8b9ac391f5e0' User entered '04 Oct 2020 21:20'	System	05 Oct 2020 01:20:25
	System	05 Oct 2020 01:20:25

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 6'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:08', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cd134991-6855-49b9-bf08-05a9020e6aaa' User entered 'Yes (Y)'	System	05 Oct 2020 20:49:21
	System	05 Oct 2020 20:49:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:14', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cd134991-6855-49b9-bf08-05a9020e6aaa' User entered '97.7'	System	05 Oct 2020 20:49:21
	System	05 Oct 2020 20:49:21

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:16', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cd134991-6855-49b9-bf08-05a9020e6aaa' User entered 'No (N)'	System	05 Oct 2020 20:49:21
	System	05 Oct 2020 20:49:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:20', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'cd134991-6855-49b9-bf08-05a9020e6aaa' User entered '05 Oct 2020 16:49'	System	05 Oct 2020 20:49:21
	System	05 Oct 2020 20:49:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 7'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:04', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'dce38caa-3162-49d0-a243-f35ec2e3e076' User entered 'Yes (Y)'	System	07 Oct 2020 00:12:18
	System	07 Oct 2020 00:12:18

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:14', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'dce38caa-3162-49d0-a243-f35ec2e3e076' User entered '97.5'	System	07 Oct 2020 00:12:18
	System	07 Oct 2020 00:12:18

US3662049

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:23', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'dce38caa-3162-49d0-a243-f35ec2e3e076' User entered 'No (N)'	System	07 Oct 2020 00:12:18
	System	07 Oct 2020 00:12:18

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:26', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'dce38caa-3162-49d0-a243-f35ec2e3e076' User entered '06 Oct 2020 20:10'	System	07 Oct 2020 00:12:18
	System	07 Oct 2020 00:12:18

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:57:09



US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '281a1d7e-52b5-419f-b4fa-fa5859103181' User entered 'None (1)'	System	30 Sep 2020 17:26:34
	System	30 Sep 2020 17:26:34

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:20', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '281a1d7e-52b5-419f-b4fa-fa5859103181' User entered 'No (N)'	System	30 Sep 2020 17:26:34
	System	30 Sep 2020 17:26:34

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:22', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '281a1d7e-52b5-419f-b4fa-fa5859103181' User entered 'No (N)'	System	30 Sep 2020 17:26:34
	System	30 Sep 2020 17:26:34

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:28', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '281a1d7e-52b5-419f-b4fa-fa5859103181' User entered 'None (1)'	System	30 Sep 2020 17:26:34
	System	30 Sep 2020 17:26:34

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:31', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '281a1d7e-52b5-419f-b4fa-fa5859103181' User entered '30 Sep 2020 13:26'	System	30 Sep 2020 17:26:34
	System	30 Sep 2020 17:26:34

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '30 Sep 2020 13:09'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '30 Sep 2020 15:39'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:57:09



US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:11', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'fc2f7bb8-0eb2-4023-8721-3d1f15e30e34' User entered 'None (1)'	System	30 Sep 2020 23:08:25
	System	30 Sep 2020 23:08:25

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:14', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'fc2f7bb8-0eb2-4023-8721-3d1f15e30e34' User entered 'No (N)'	System	30 Sep 2020 23:08:25
	System	30 Sep 2020 23:08:25

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:17', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'fc2f7bb8-0eb2-4023-8721-3d1f15e30e34' User entered 'No (N)'	System	30 Sep 2020 23:08:25
	System	30 Sep 2020 23:08:25

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:20', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'fc2f7bb8-0eb2-4023-8721-3d1f15e30e34' User entered 'None (1)'	System	30 Sep 2020 23:08:25
	System	30 Sep 2020 23:08:25

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:22', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'fc2f7bb8-0eb2-4023-8721-3d1f15e30e34' User entered '30 Sep 2020 19:08'	System	30 Sep 2020 23:08:25
	System	30 Sep 2020 23:08:25

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '30 Sep 2020 16:34'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 2'	System	30 Sep 2020 16:57:09



US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:10', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a7440615-f5cd-4ea4-942a-eaf6731a0d9b'	System	01 Oct 2020 22:09:50
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 22:09:50

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:15', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a7440615-f5cd-4ea4-942a-eaf6731a0d9b' User entered 'Yes (Y)'	System	01 Oct 2020 22:09:50
	System	01 Oct 2020 22:09:50

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**Please record - REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:27', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a7440615-f5cd-4ea4-942a-eaf6731a0d9b' User entered '1'	System	01 Oct 2020 22:09:50
	System	01 Oct 2020 22:09:50

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:33', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a7440615-f5cd-4ea4-942a-eaf6731a0d9b' User entered 'Yes (Y)'	System	01 Oct 2020 22:09:50
	System	01 Oct 2020 22:09:50

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:50

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:38', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a7440615-f5cd-4ea4-942a-eaf6731a0d9b' User entered '1'	System	01 Oct 2020 22:09:50
	System	01 Oct 2020 22:09:50

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:41', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a7440615-f5cd-4ea4-942a-eaf6731a0d9b'	System	01 Oct 2020 22:09:50
User entered 'None (1)'	System	01 Oct 2020 22:09:50

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:46', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a7440615-f5cd-4ea4-942a-eaf6731a0d9b' User entered '01 Oct 2020 18:09'	System	01 Oct 2020 22:09:50
	System	01 Oct 2020 22:09:50

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 3'	System	30 Sep 2020 16:57:09

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:33', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'd9274816-0d48-4b08-9573-e62ec4f40278'	System	02 Oct 2020 20:47:53
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 20:47:53

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:41', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'd9274816-0d48-4b08-9573-e62ec4f40278' User entered 'No (N)'	System	02 Oct 2020 20:47:53
	System	02 Oct 2020 20:47:53

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:43', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'd9274816-0d48-4b08-9573-e62ec4f40278' User entered 'No (N)'	System	02 Oct 2020 20:47:53
	System	02 Oct 2020 20:47:53

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:48', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'd9274816-0d48-4b08-9573-e62ec4f40278' User entered 'None (1)'	System	02 Oct 2020 20:47:53
	System	02 Oct 2020 20:47:53

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'd9274816-0d48-4b08-9573-e62ec4f40278' User entered '02 Oct 2020 16:47'	System	02 Oct 2020 20:47:53
	System	02 Oct 2020 20:47:53

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 4'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**Please record - PAIN AT INJECTION SITE.**

**Please select one response below**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:47:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a13c4c56-0f03-42ae-a777-276a01b0f172'	System	04 Oct 2020 12:48:09
User entered 'None (1)'	System	04 Oct 2020 12:48:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:47:57', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a13c4c56-0f03-42ae-a777-276a01b0f172' User entered 'No (N)'	System	04 Oct 2020 12:48:09
	System	04 Oct 2020 12:48:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a13c4c56-0f03-42ae-a777-276a01b0f172'	System	04 Oct 2020 12:48:09
User entered 'No (N)'	System	04 Oct 2020 12:48:09

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:04', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a13c4c56-0f03-42ae-a777-276a01b0f172'	System	04 Oct 2020 12:48:09
User entered 'None (1)'	System	04 Oct 2020 12:48:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:07', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a13c4c56-0f03-42ae-a777-276a01b0f172' User entered '04 Oct 2020 08:48'	System	04 Oct 2020 12:48:09
	System	04 Oct 2020 12:48:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 5'	System	30 Sep 2020 16:57:09

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:31', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2f3ea497-79ef-4e7f-a0c8-d3c215c2ac2f' User entered 'None (1)'	System	05 Oct 2020 01:20:46
	System	05 Oct 2020 01:20:46

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:35', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2f3ea497-79ef-4e7f-a0c8-d3c215c2ac2f' User entered 'No (N)'	System	05 Oct 2020 01:20:46
	System	05 Oct 2020 01:20:46

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:37', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2f3ea497-79ef-4e7f-a0c8-d3c215c2ac2f' User entered 'No (N)'	System	05 Oct 2020 01:20:46
	System	05 Oct 2020 01:20:46

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:41', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2f3ea497-79ef-4e7f-a0c8-d3c215c2ac2f' User entered 'None (1)'	System	05 Oct 2020 01:20:46
	System	05 Oct 2020 01:20:46

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:44', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '2f3ea497-79ef-4e7f-a0c8-d3c215c2ac2f' User entered '04 Oct 2020 21:20'	System	05 Oct 2020 01:20:46
	System	05 Oct 2020 01:20:46

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 6'	System	30 Sep 2020 16:57:09

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:25', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf92176-25a2-4ef4-b0b6-fbdc5a39023a' User entered 'None (1)'	System	05 Oct 2020 20:49:39
	System	05 Oct 2020 20:49:39

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:30', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf92176-25a2-4ef4-b0b6-fbdc5a39023a' User entered 'No (N)'	System	05 Oct 2020 20:49:39
	System	05 Oct 2020 20:49:39

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:32', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf92176-25a2-4ef4-b0b6-fbdc5a39023a' User entered 'No (N)'	System	05 Oct 2020 20:49:39
	System	05 Oct 2020 20:49:39

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:35', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf92176-25a2-4ef4-b0b6-fbdc5a39023a' User entered 'None (1)'	System	05 Oct 2020 20:49:39
	System	05 Oct 2020 20:49:39

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:37', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4cf92176-25a2-4ef4-b0b6-fbdc5a39023a' User entered '05 Oct 2020 16:49'	System	05 Oct 2020 20:49:39
	System	05 Oct 2020 20:49:39

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 7'	System	30 Sep 2020 16:57:09

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:50

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:29', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'afbda4b0-9cdd-4eb3-b4ba-0dc1db10a757'	System	07 Oct 2020 00:12:24
User entered 'None (1)'	System	07 Oct 2020 00:12:24

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:33', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'afbda4b0-9cdd-4eb3-b4ba-0dc1db10a757' User entered 'No (N)'	System	07 Oct 2020 00:12:24
	System	07 Oct 2020 00:12:24

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:36', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'afbda4b0-9cdd-4eb3-b4ba-0dc1db10a757'	System	07 Oct 2020 00:12:24
User entered 'No (N)'	System	07 Oct 2020 00:12:24

US3662049

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:50

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:37', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'afbda4b0-9cdd-4eb3-b4ba-0dc1db10a757'	System	07 Oct 2020 00:12:24
User entered 'None (1)'	System	07 Oct 2020 00:12:24

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:39', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'afbda4b0-9cdd-4eb3-b4ba-0dc1db10a757' User entered '06 Oct 2020 20:10'	System	07 Oct 2020 00:12:24
	System	07 Oct 2020 00:12:24

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:36', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a27c9417-8205-4919-9313-dbc39285fa55' User entered 'None (0)'	System	30 Sep 2020 17:26:57
	System	30 Sep 2020 17:26:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:38', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a27c9417-8205-4919-9313-dbc39285fa55' User entered 'None (0)'	System	30 Sep 2020 17:26:57
	System	30 Sep 2020 17:26:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:40', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a27c9417-8205-4919-9313-dbc39285fa55' User entered 'None (0)'	System	30 Sep 2020 17:26:57
	System	30 Sep 2020 17:26:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:43', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a27c9417-8205-4919-9313-dbc39285fa55' User entered 'None (0)'	System	30 Sep 2020 17:26:57
	System	30 Sep 2020 17:26:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:46', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a27c9417-8205-4919-9313-dbc39285fa55' User entered 'None (0)'	System	30 Sep 2020 17:26:57
	System	30 Sep 2020 17:26:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:48', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a27c9417-8205-4919-9313-dbc39285fa55' User entered 'None (0)'	System	30 Sep 2020 17:26:57
	System	30 Sep 2020 17:26:57



US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:50

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:52', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a27c9417-8205-4919-9313-dbc39285fa55' User entered 'No (N)'	System	30 Sep 2020 17:26:57
	System	30 Sep 2020 17:26:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T13:26:55', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a27c9417-8205-4919-9313-dbc39285fa55' User entered '30 Sep 2020 13:26'	System	30 Sep 2020 17:26:57
	System	30 Sep 2020 17:26:57

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '30 Sep 2020 13:09'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '30 Sep 2020 15:39'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:28', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f94faffe-09ff-4e5f-a53b-be1a2c6cb548' User entered 'None (0)'	System	30 Sep 2020 23:08:55
	System	30 Sep 2020 23:08:55

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:32', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f94faffe-09ff-4e5f-a53b-be1a2c6cb548' User entered 'None (0)'	System	30 Sep 2020 23:08:55
	System	30 Sep 2020 23:08:55

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:36', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f94faffe-09ff-4e5f-a53b-be1a2c6cb548' User entered 'None (0)'	System	30 Sep 2020 23:08:55
	System	30 Sep 2020 23:08:55



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:38', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f94faffe-09ff-4e5f-a53b-be1a2c6cb548' User entered 'None (0)'	System	30 Sep 2020 23:08:55
	System	30 Sep 2020 23:08:55

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:43', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f94faffe-09ff-4e5f-a53b-be1a2c6cb548' User entered 'None (0)'	System	30 Sep 2020 23:08:55
	System	30 Sep 2020 23:08:55

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:45', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f94faffe-09ff-4e5f-a53b-be1a2c6cb548' User entered 'None (0)'	System	30 Sep 2020 23:08:55
	System	30 Sep 2020 23:08:55

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:49', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f94faffe-09ff-4e5f-a53b-be1a2c6cb548' User entered 'No (N)'	System	30 Sep 2020 23:08:55
	System	30 Sep 2020 23:08:55

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-09-30T19:08:52', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'f94faffe-09ff-4e5f-a53b-be1a2c6cb548' User entered '30 Sep 2020 19:08'	System	30 Sep 2020 23:08:55
	System	30 Sep 2020 23:08:55

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '30 Sep 2020 16:34'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 2'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5e92c883-bcde-4d09-8537-ba9cfa768cc8' User entered 'None (0)'	System	01 Oct 2020 22:10:21
	System	01 Oct 2020 22:10:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5e92c883-bcde-4d09-8537-ba9cfa768cc8' User entered 'None (0)'	System	01 Oct 2020 22:10:21
	System	01 Oct 2020 22:10:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:09:58', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5e92c883-bcde-4d09-8537-ba9cfa768cc8' User entered 'None (0)'	System	01 Oct 2020 22:10:21
	System	01 Oct 2020 22:10:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:10:01', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5e92c883-bcde-4d09-8537-ba9cfa768cc8' User entered 'None (0)'	System	01 Oct 2020 22:10:21
	System	01 Oct 2020 22:10:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:10:04', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5e92c883-bcde-4d09-8537-ba9cfa768cc8' User entered 'None (0)'	System	01 Oct 2020 22:10:21
	System	01 Oct 2020 22:10:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:10:07', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5e92c883-bcde-4d09-8537-ba9cfa768cc8' User entered 'None (0)'	System	01 Oct 2020 22:10:21
	System	01 Oct 2020 22:10:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:10:12', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5e92c883-bcde-4d09-8537-ba9cfa768cc8' User entered 'No (N)'	System	01 Oct 2020 22:10:21
	System	01 Oct 2020 22:10:21

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-01T18:10:17', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5e92c883-bcde-4d09-8537-ba9cfa768cc8' User entered '01 Oct 2020 18:10'	System	01 Oct 2020 22:10:21
	System	01 Oct 2020 22:10:21



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 3'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:55', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '77f49862-264c-4982-bbeb-6419f31f632b' User entered 'None (0)'	System	02 Oct 2020 20:48:19
	System	02 Oct 2020 20:48:19

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:47:57', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '77f49862-264c-4982-bbeb-6419f31f632b' User entered 'None (0)'	System	02 Oct 2020 20:48:19
	System	02 Oct 2020 20:48:19

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:48:03', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '77f49862-264c-4982-bbeb-6419f31f632b' User entered 'None (0)'	System	02 Oct 2020 20:48:19
	System	02 Oct 2020 20:48:19

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:48:06', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '77f49862-264c-4982-bbeb-6419f31f632b' User entered 'None (0)'	System	02 Oct 2020 20:48:19
	System	02 Oct 2020 20:48:19

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:48:08', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '77f49862-264c-4982-bbeb-6419f31f632b' User entered 'None (0)'	System	02 Oct 2020 20:48:19
	System	02 Oct 2020 20:48:19



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:48:10', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '77f49862-264c-4982-bbeb-6419f31f632b' User entered 'None (0)'	System	02 Oct 2020 20:48:19
	System	02 Oct 2020 20:48:19

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:48:16', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '77f49862-264c-4982-bbeb-6419f31f632b' User entered 'No (N)'	System	02 Oct 2020 20:48:19
	System	02 Oct 2020 20:48:19

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-02T16:48:18', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '77f49862-264c-4982-bbeb-6419f31f632b' User entered '02 Oct 2020 16:48'	System	02 Oct 2020 20:48:19
	System	02 Oct 2020 20:48:19

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 4'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:12', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a20939a3-ac90-4509-8362-214855a374a9' User entered 'None (0)'	System	04 Oct 2020 12:48:35
	System	04 Oct 2020 12:48:35

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:15', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a20939a3-ac90-4509-8362-214855a374a9' User entered 'None (0)'	System	04 Oct 2020 12:48:35
	System	04 Oct 2020 12:48:35



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:19', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a20939a3-ac90-4509-8362-214855a374a9' User entered 'None (0)'	System	04 Oct 2020 12:48:35
	System	04 Oct 2020 12:48:35

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:22', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a20939a3-ac90-4509-8362-214855a374a9' User entered 'None (0)'	System	04 Oct 2020 12:48:35
	System	04 Oct 2020 12:48:35

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:25', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a20939a3-ac90-4509-8362-214855a374a9' User entered 'None (0)'	System	04 Oct 2020 12:48:35
	System	04 Oct 2020 12:48:35

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:27', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a20939a3-ac90-4509-8362-214855a374a9' User entered 'None (0)'	System	04 Oct 2020 12:48:35
	System	04 Oct 2020 12:48:35

US3662049

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:50

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:30', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a20939a3-ac90-4509-8362-214855a374a9' User entered 'No (N)'	System	04 Oct 2020 12:48:35
	System	04 Oct 2020 12:48:35

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T08:48:32', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'a20939a3-ac90-4509-8362-214855a374a9' User entered '04 Oct 2020 08:48'	System	04 Oct 2020 12:48:35
	System	04 Oct 2020 12:48:35

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 5'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:48', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5463de12-0169-4a33-ba5a-80ebbe0aa759' User entered 'None (0)'	System	05 Oct 2020 01:21:08
	System	05 Oct 2020 01:21:08

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:50', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5463de12-0169-4a33-ba5a-80ebbe0aa759' User entered 'None (0)'	System	05 Oct 2020 01:21:08
	System	05 Oct 2020 01:21:08

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:53', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5463de12-0169-4a33-ba5a-80ebbe0aa759' User entered 'None (0)'	System	05 Oct 2020 01:21:08
	System	05 Oct 2020 01:21:08

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:55', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5463de12-0169-4a33-ba5a-80ebbe0aa759' User entered 'None (0)'	System	05 Oct 2020 01:21:08
	System	05 Oct 2020 01:21:08

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:20:57', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5463de12-0169-4a33-ba5a-80ebbe0aa759' User entered 'None (0)'	System	05 Oct 2020 01:21:08
	System	05 Oct 2020 01:21:08

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:21:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5463de12-0169-4a33-ba5a-80ebbe0aa759' User entered 'None (0)'	System	05 Oct 2020 01:21:08
	System	05 Oct 2020 01:21:08

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:21:03', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5463de12-0169-4a33-ba5a-80ebbe0aa759' User entered 'No (N)'	System	05 Oct 2020 01:21:08
	System	05 Oct 2020 01:21:08



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-04T21:21:05', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5463de12-0169-4a33-ba5a-80ebbe0aa759' User entered '04 Oct 2020 21:21'	System	05 Oct 2020 01:21:08
	System	05 Oct 2020 01:21:08

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 6'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:40', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e9dd5393-b60e-41bd-9a3c-807b41f50a42' User entered 'None (0)'	System	05 Oct 2020 20:50:07
	System	05 Oct 2020 20:50:07

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:42', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e9dd5393-b60e-41bd-9a3c-807b41f50a42' User entered 'None (0)'	System	05 Oct 2020 20:50:07
	System	05 Oct 2020 20:50:07

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:45', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e9dd5393-b60e-41bd-9a3c-807b41f50a42' User entered 'None (0)'	System	05 Oct 2020 20:50:07
	System	05 Oct 2020 20:50:07

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:49', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e9dd5393-b60e-41bd-9a3c-807b41f50a42' User entered 'None (0)'	System	05 Oct 2020 20:50:07
	System	05 Oct 2020 20:50:07



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e9dd5393-b60e-41bd-9a3c-807b41f50a42' User entered 'None (0)'	System	05 Oct 2020 20:50:07
	System	05 Oct 2020 20:50:07

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:49:56', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e9dd5393-b60e-41bd-9a3c-807b41f50a42' User entered 'None (0)'	System	05 Oct 2020 20:50:07
	System	05 Oct 2020 20:50:07

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:50:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e9dd5393-b60e-41bd-9a3c-807b41f50a42'	System	05 Oct 2020 20:50:07
User entered 'No (N)'	System	05 Oct 2020 20:50:07

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-05T16:50:04', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e9dd5393-b60e-41bd-9a3c-807b41f50a42' User entered '05 Oct 2020 16:50'	System	05 Oct 2020 20:50:07
	System	05 Oct 2020 20:50:07

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	30 Sep 2020 16:57:09
User entered 'Day 7'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:43', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b882b0fc-9a17-4043-8630-871eb4ef7c98' User entered 'None (0)'	System	07 Oct 2020 00:12:33
	System	07 Oct 2020 00:12:33



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:45', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b882b0fc-9a17-4043-8630-871eb4ef7c98' User entered 'None (0)'	System	07 Oct 2020 00:12:33
	System	07 Oct 2020 00:12:33

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:49', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b882b0fc-9a17-4043-8630-871eb4ef7c98' User entered 'None (0)'	System	07 Oct 2020 00:12:33
	System	07 Oct 2020 00:12:33

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b882b0fc-9a17-4043-8630-871eb4ef7c98' User entered 'None (0)'	System	07 Oct 2020 00:12:33
	System	07 Oct 2020 00:12:33

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:53', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b882b0fc-9a17-4043-8630-871eb4ef7c98' User entered 'None (0)'	System	07 Oct 2020 00:12:33
	System	07 Oct 2020 00:12:33

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:10:57', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b882b0fc-9a17-4043-8630-871eb4ef7c98' User entered 'None (0)'	System	07 Oct 2020 00:12:33
	System	07 Oct 2020 00:12:33

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:11:03', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b882b0fc-9a17-4043-8630-871eb4ef7c98'	System	07 Oct 2020 00:12:33
User entered 'No (N)'	System	07 Oct 2020 00:12:33

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77AFD39E-94F9-4476-9399-8D58D043EC5D)', Time: '2020-10-06T20:11:05', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b882b0fc-9a17-4043-8630-871eb4ef7c98' User entered '06 Oct 2020 20:11'	System	07 Oct 2020 00:12:33
	System	07 Oct 2020 00:12:33

**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:57:09



**US3662049**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:57:09

**US3662049**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Oct 2020 17:45:37

**US3662049**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '07 Oct 2020'	Brenda Miller (b) (4)	08 Oct 2020 17:45:37

**US3662049**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	08 Oct 2020 17:45:37

**US3662049**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	08 Oct 2020 17:45:37

**US3662049**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Oct 2020 17:45:43

**US3662049**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'I'	System	08 Oct 2020 17:45:43

**US3662049**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Oct 2020 13:56:55



**US3662049**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '15 Oct 2020'	Brenda Miller (b) (4)	16 Oct 2020 13:56:55

**US3662049**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	16 Oct 2020 13:56:55

**US3662049**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	16 Oct 2020 13:56:55

**US3662049**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Oct 2020 13:57:01

**US3662049**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'I'	System	16 Oct 2020 13:57:01

**US3662049**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	26 Oct 2020 12:28:43

**US3662049**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '22 Oct 2020'	Brenda Miller (b) (4)	26 Oct 2020 12:28:43

**US3662049**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	26 Oct 2020 12:28:43



**US3662049**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	26 Oct 2020 12:28:43

**US3662049**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	26 Oct 2020 12:28:50

**US3662049**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'I'	System	26 Oct 2020 12:28:50

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:25:36

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:25:36

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:25:36

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'VISIT3'	System	28 Oct 2020 14:25:36

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	29 Oct 2020 12:17:32



**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '28 Oct 2020'	Brenda Miller (b) (4)	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '10:15'	Brenda Miller (b) (4)	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '28 Oct 2020 10:15'	System	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '97.7' F	Brenda Miller (b) (4)	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Other (Other)'	Brenda Miller (b) (4)	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '85'	Brenda Miller (b) (4)	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'bpm'	System	29 Oct 2020 12:17:32



**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '20'	Brenda Miller (b) (4)	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'breaths/min'	System	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '150'	Brenda Miller (b) (4)	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '97'	Brenda Miller (b) (4)	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'mmHg'	System	29 Oct 2020 12:17:32

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06



**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	29 Oct 2020 12:17:43

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '28 Oct 2020'	Brenda Miller (b) (4)	29 Oct 2020 12:17:43

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Brenda Miller (b) (4)	29 Oct 2020 12:18:10

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '28 Oct 2020'	Brenda Miller (b) (4)	29 Oct 2020 12:18:10

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '10:20'	Brenda Miller (b) (4)	29 Oct 2020 12:18:10

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered '28 Oct 2020 10:20'	System	29 Oct 2020 12:18:10

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:25:56

**US3662049**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'I'	System	28 Oct 2020 14:25:56



**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 64'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07
Data entry locked.	System	03 Sep 2020 19:47:38
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:29:07
Data entry locked.	System	03 Sep 2020 19:47:38
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 71'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-11-10T10:39:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '07bb3365-4788-4ca8-9704-c73d0bc6d0'	System	10 Nov 2020 15:40:05
User entered 'No (N)'	System	10 Nov 2020 15:40:05

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-11-10T10:39:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '07bb3365-4788-4ca8-9704-c73d0bcd6d0'	System	10 Nov 2020 15:40:05
User entered 'No (N)'	System	10 Nov 2020 15:40:05

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-11-10T10:39:58', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '07bb3365-4788-4ca8-9704-c73d0bcd6d0'	System	10 Nov 2020 15:40:05
User entered '10 Nov 2020 10:39:58'	System	10 Nov 2020 15:40:05



**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered 'Day 78'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-11-17T11:13:08', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '26f27e10-99c7-4eae-aebd-6d45a4b35ac4'	System	17 Nov 2020 16:13:23
User entered 'No (N)'	System	17 Nov 2020 16:13:23

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-11-17T11:13:12', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '26f27e10-99c7-4eae-aebd-6d45a4b35ac4'	System	17 Nov 2020 16:13:23
User entered 'No (N)'	System	17 Nov 2020 16:13:23

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-11-17T11:13:19', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '26f27e10-99c7-4eae-aebd-6d45a4b35ac4'	System	17 Nov 2020 16:13:23
User entered '17 Nov 2020 11:13:19'	System	17 Nov 2020 16:13:23

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 19:47:38

**US3662049**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:37:08
Data entry locked.	System	03 Sep 2020 19:47:38
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 19:47:38



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-11-24T14:03:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5570efa8-f342-423f-9a19-ae7ac41f5567'	System	24 Nov 2020 19:04:06
User entered 'No (N)'	System	24 Nov 2020 19:04:06

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-11-24T14:03:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5570efa8-f342-423f-9a19-ae7ac41f5567'	System	24 Nov 2020 19:04:06
User entered 'No (N)'	System	24 Nov 2020 19:04:06

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-11-24T14:03:59', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5570efa8-f342-423f-9a19-ae7ac41f5567'	System	24 Nov 2020 19:04:06
User entered '24 Nov 2020 14:03:59'	System	24 Nov 2020 19:04:06

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-01T08:54:37', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '92cba176-77de-401a-b743-d6a25d745596'	System	01 Dec 2020 13:54:57
User entered 'No (N)'	System	01 Dec 2020 13:54:57



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-01T08:54:42', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '92cba176-77de-401a-b743-d6a25d745596'	System	01 Dec 2020 13:54:57
User entered 'No (N)'	System	01 Dec 2020 13:54:57

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-01T08:54:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '92cba176-77de-401a-b743-d6a25d745596'	System	01 Dec 2020 13:54:57
User entered '01 Dec 2020 08:54:51'	System	01 Dec 2020 13:54:57

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-08T19:34:33', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0a39cb3d-4ada-4339-bbaa-993712691f16'	System	09 Dec 2020 00:34:50
User entered 'No (N)'	System	09 Dec 2020 00:34:50

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-08T19:34:39', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0a39cb3d-4ada-4339-bbaa-993712691f16'	System	09 Dec 2020 00:34:50
User entered 'No (N)'	System	09 Dec 2020 00:34:50

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-08T19:34:46', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '0a39cb3d-4ada-4339-bbaa-993712691f16'	System	09 Dec 2020 00:34:50
User entered '08 Dec 2020 19:34:46'	System	09 Dec 2020 00:34:50



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-15T08:17:39', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '62fbb89a-6a85-444d-8582-53094980ed12'	System	15 Dec 2020 13:17:54
User entered 'No (N)'	System	15 Dec 2020 13:17:54

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-15T08:17:44', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '62fbb89a-6a85-444d-8582-53094980ed12'	System	15 Dec 2020 13:17:54
User entered 'No (N)'	System	15 Dec 2020 13:17:54

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-15T08:17:50', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '62fbb89a-6a85-444d-8582-53094980ed12'	System	15 Dec 2020 13:17:54
User entered '15 Dec 2020 08:17:50'	System	15 Dec 2020 13:17:54

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-22T11:54:42', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e6147f16-08ce-48ab-8c79-1b8715f90703'	System	22 Dec 2020 16:54:54
User entered 'No (N)'	System	22 Dec 2020 16:54:54

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-22T11:54:45', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e6147f16-08ce-48ab-8c79-1b8715f90703'	System	22 Dec 2020 16:54:54
User entered 'No (N)'	System	22 Dec 2020 16:54:54

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-22T11:54:50', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e6147f16-08ce-48ab-8c79-1b8715f90703' User entered '22 Dec 2020 11:54:50'	System	22 Dec 2020 16:54:54
	System	22 Dec 2020 16:54:54

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-29T10:25:51', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4b313826-ad0f-473f-9bec-ecf57a354bec'	System	29 Dec 2020 15:26:06
User entered 'No (N)'	System	29 Dec 2020 15:26:06



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-29T10:25:54', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4b313826-ad0f-473f-9bec-ecf57a354bec'	System	29 Dec 2020 15:26:06
User entered 'No (N)'	System	29 Dec 2020 15:26:06

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2020-12-29T10:25:58', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4b313826-ad0f-473f-9bec-ecf57a354bec' User entered '29 Dec 2020 10:25:58'	System	29 Dec 2020 15:26:06
	System	29 Dec 2020 15:26:06

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-06T07:00:31', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '8a5021f9-deef-47ba-9898-b90ee879986d'	System	06 Jan 2021 12:00:48
User entered 'No (N)'	System	06 Jan 2021 12:00:48

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-06T07:00:41', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '8a5021f9-deef-47ba-9898-b90ee879986d'	System	06 Jan 2021 12:00:48
User entered 'No (N)'	System	06 Jan 2021 12:00:48

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-06T07:00:44', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '8a5021f9-deef-47ba-9898-b90ee879986d'	System	06 Jan 2021 12:00:48
User entered '06 Jan 2021 07:00:44'	System	06 Jan 2021 12:00:48



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-12T06:45:04', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ecb17cc2-3fd5-472b-a94a-6ab6b43d2c36'	System	12 Jan 2021 11:45:20
User entered 'No (N)'	System	12 Jan 2021 11:45:20

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-12T06:45:12', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ecb17cc2-3fd5-472b-a94a-6ab6b43d2c36'	System	12 Jan 2021 11:45:20
User entered 'No (N)'	System	12 Jan 2021 11:45:20

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-12T06:45:15', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ecb17cc2-3fd5-472b-a94a-6ab6b43d2c36'	System	12 Jan 2021 11:45:20
User entered '12 Jan 2021 06:45:15'	System	12 Jan 2021 11:45:20

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-19T10:03:37', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ef5dbb94-0666-47a4-ad08-0a56a7fe94c5'	System	19 Jan 2021 15:03:52
User entered 'No (N)'	System	19 Jan 2021 15:03:52

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-19T10:03:42', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ef5dbb94-0666-47a4-ad08-0a56a7fe94c5'	System	19 Jan 2021 15:03:52
User entered 'No (N)'	System	19 Jan 2021 15:03:52

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-19T10:03:47', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ef5dbb94-0666-47a4-ad08-0a56a7fe94c5'	System	19 Jan 2021 15:03:52
User entered '19 Jan 2021 10:03:47'	System	19 Jan 2021 15:03:52

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-26T07:36:24', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '6ca4b24e-5579-4ca8-9918-4a1d584dc745'	System	26 Jan 2021 12:36:36
User entered 'No (N)'	System	26 Jan 2021 12:36:36



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-26T07:36:27', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '6ca4b24e-5579-4ca8-9918-4a1d584dc745'	System	26 Jan 2021 12:36:36
User entered 'No (N)'	System	26 Jan 2021 12:36:36

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-01-26T07:36:31', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '6ca4b24e-5579-4ca8-9918-4a1d584dc745'	System	26 Jan 2021 12:36:36
User entered '26 Jan 2021 07:36:31'	System	26 Jan 2021 12:36:36

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-02T08:03:24', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b2e57436-2e6b-482b-848f-1904f0355bb4'	System	02 Feb 2021 13:03:35
User entered 'No (N)'	System	02 Feb 2021 13:03:35

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-02T08:03:27', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b2e57436-2e6b-482b-848f-1904f0355bb4'	System	02 Feb 2021 13:03:35
User entered 'No (N)'	System	02 Feb 2021 13:03:35

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-02T08:03:30', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'b2e57436-2e6b-482b-848f-1904f0355bb4'	System	02 Feb 2021 13:03:35
User entered '02 Feb 2021 08:03:30'	System	02 Feb 2021 13:03:35



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-09T15:52:04', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1087f0d7-2faf-45cd-a8d3-6a55a6ec15b9'	System	09 Feb 2021 20:52:14
User entered 'No (N)'	System	09 Feb 2021 20:52:14

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-09T15:52:06', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1087f0d7-2faf-45cd-a8d3-6a55a6ec15b9'	System	09 Feb 2021 20:52:14
User entered 'No (N)'	System	09 Feb 2021 20:52:14

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-09T15:52:10', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '1087f0d7-2faf-45cd-a8d3-6a55a6ec15b9'	System	09 Feb 2021 20:52:14
User entered '09 Feb 2021 15:52:10'	System	09 Feb 2021 20:52:14

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-16T14:06:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '97fe8213-0dfb-4859-a188-c31d69547296'	System	16 Feb 2021 19:06:12
User entered 'No (N)'	System	16 Feb 2021 19:06:12

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-16T14:06:02', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '97fe8213-0dfb-4859-a188-c31d69547296'	System	16 Feb 2021 19:06:12
User entered 'No (N)'	System	16 Feb 2021 19:06:12

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-16T14:06:07', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '97fe8213-0dfb-4859-a188-c31d69547296'	System	16 Feb 2021 19:06:12
User entered '16 Feb 2021 14:06:07'	System	16 Feb 2021 19:06:12

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-23T08:39:18-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4d672229-7f33-45af-baca-c06a510a1067'	System	23 Feb 2021 13:39:32
User entered 'No (N)'	System	23 Feb 2021 13:39:32



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-23T08:39:22-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4d672229-7f33-45af-baca-c06a510a1067'	System	23 Feb 2021 13:39:32
User entered 'No (N)'	System	23 Feb 2021 13:39:32

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-02-23T08:39:28-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '4d672229-7f33-45af-baca-c06a510a1067'	System	23 Feb 2021 13:39:32
User entered '23 Feb 2021 08:39:28'	System	23 Feb 2021 13:39:32

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-03T11:58:46-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ba38c9a9-b938-4c80-b45f-1dbf3f64be94'	System	03 Mar 2021 16:59:53
User entered 'No (N)'	System	03 Mar 2021 16:59:53

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-03T11:58:48-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ba38c9a9-b938-4c80-b45f-1dbf3f64be94'	System	03 Mar 2021 16:59:53
User entered 'No (N)'	System	03 Mar 2021 16:59:53

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-03T11:58:51-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'ba38c9a9-b938-4c80-b45f-1dbf3f64be94'	System	03 Mar 2021 16:59:53
User entered '03 Mar 2021 11:58:51'	System	03 Mar 2021 16:59:53



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-09T07:53:58-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e40a9205-2624-44bc-9f13-f1d6d1f5efcb'	System	09 Mar 2021 12:54:10
User entered 'No (N)'	System	09 Mar 2021 12:54:10

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-09T07:54:01-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e40a9205-2624-44bc-9f13-f1d6d1f5efcb'	System	09 Mar 2021 12:54:10
User entered 'No (N)'	System	09 Mar 2021 12:54:10

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-09T07:54:05-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e40a9205-2624-44bc-9f13-f1d6d1f5efcb' User entered '09 Mar 2021 07:54:05'	System	09 Mar 2021 12:54:10
	System	09 Mar 2021 12:54:10

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-16T11:29:13-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '56f59c5c-9936-4452-85dd-bbc2ab7fc8eb'	System	16 Mar 2021 15:29:26
User entered 'No (N)'	System	16 Mar 2021 15:29:26

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-16T11:29:16-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '56f59c5c-9936-4452-85dd-bbc2ab7fc8eb'	System	16 Mar 2021 15:29:26
User entered 'No (N)'	System	16 Mar 2021 15:29:26

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-16T11:29:20-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '56f59c5c-9936-4452-85dd-bbc2ab7fc8eb'	System	16 Mar 2021 15:29:26
User entered '16 Mar 2021 11:29:20'	System	16 Mar 2021 15:29:26

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-23T13:13:06-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e98a7563-3692-49aa-900b-c86c95a52e82'	System	23 Mar 2021 17:13:38
User entered 'No (N)'	System	23 Mar 2021 17:13:38



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-23T13:13:08-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e98a7563-3692-49aa-900b-c86c95a52e82'	System	23 Mar 2021 17:13:38
User entered 'No (N)'	System	23 Mar 2021 17:13:38

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-23T13:13:11-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e98a7563-3692-49aa-900b-c86c95a52e82'	System	23 Mar 2021 17:13:38
User entered '23 Mar 2021 13:13:11'	System	23 Mar 2021 17:13:38

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-30T10:56:06-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e8203fef-9f90-4cc4-ad4d-6510bd93f013'	System	30 Mar 2021 14:56:18
User entered 'No (N)'	System	30 Mar 2021 14:56:18

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-30T10:56:08-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e8203fef-9f90-4cc4-ad4d-6510bd93f013'	System	30 Mar 2021 14:56:18
User entered 'No (N)'	System	30 Mar 2021 14:56:18

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-30T10:56:11-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: 'e8203fef-9f90-4cc4-ad4d-6510bd93f013'	System	30 Mar 2021 14:56:18
User entered '30 Mar 2021 10:56:11'	System	30 Mar 2021 14:56:18



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-06T10:32:38-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5b44a479-c9d0-409a-90d2-24d795879da7'	System	06 Apr 2021 14:32:50
User entered 'No (N)'	System	06 Apr 2021 14:32:50

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-06T10:32:41-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5b44a479-c9d0-409a-90d2-24d795879da7'	System	06 Apr 2021 14:32:50
User entered 'No (N)'	System	06 Apr 2021 14:32:50

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-06T10:32:44-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '5b44a479-c9d0-409a-90d2-24d795879da7'	System	06 Apr 2021 14:32:50
User entered '06 Apr 2021 10:32:44'	System	06 Apr 2021 14:32:50

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-13T10:20:16-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52d07bfd-9baa-4e45-ad25-634e5e08a3be' User entered 'Yes (Y)'	System	13 Apr 2021 14:21:00
	System	13 Apr 2021 14:21:00

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-13T10:20:20-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52d07bfd-9baa-4e45-ad25-634e5e08a3be'	System	13 Apr 2021 14:21:00
User entered 'No (N)'	System	13 Apr 2021 14:21:00

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-13T10:20:25-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52d07bfd-9baa-4e45-ad25-634e5e08a3be' User entered 'No (N)'	System	13 Apr 2021 14:21:00
	System	13 Apr 2021 14:21:00

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-13T10:20:36-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52d07bfd-9baa-4e45-ad25-634e5e08a3be' User entered 'Yes (Y)'	System	13 Apr 2021 14:21:00
	System	13 Apr 2021 14:21:00

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-13T10:20:44-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52d07bfd-9baa-4e45-ad25-634e5e08a3be'	System	13 Apr 2021 14:21:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Apr 2021 14:21:00

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-13T10:20:47-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '52d07bfd-9baa-4e45-ad25-634e5e08a3be'	System	13 Apr 2021 14:21:00
User entered '13 Apr 2021 10:20:47'	System	13 Apr 2021 14:21:00

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-20T11:04:05-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '077b754a-3408-47d2-8c75-c30292a05709'	System	20 Apr 2021 15:04:16
User entered 'No (N)'	System	20 Apr 2021 15:04:16

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-20T11:04:09-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '077b754a-3408-47d2-8c75-c30292a05709'	System	20 Apr 2021 15:04:16
User entered 'No (N)'	System	20 Apr 2021 15:04:16

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-20T11:04:13-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '077b754a-3408-47d2-8c75-c30292a05709'	System	20 Apr 2021 15:04:16
User entered '20 Apr 2021 11:04:13'	System	20 Apr 2021 15:04:16

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-27T10:57:01-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '50d8e0f1-9d4e-4bd9-ad44-dbd19491d704'	System	29 Apr 2021 02:40:50
User entered 'No (N)'	System	29 Apr 2021 02:40:50

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-27T10:57:03-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '50d8e0f1-9d4e-4bd9-ad44-dbd19491d704'	System	29 Apr 2021 02:40:50
User entered 'No (N)'	System	29 Apr 2021 02:40:50

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-04-27T10:57:06-04:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '50d8e0f1-9d4e-4bd9-ad44-dbd19491d704'	System	29 Apr 2021 02:40:50
User entered '27 Apr 2021 10:57:06'	System	29 Apr 2021 02:40:50

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:29:07



**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:29:07
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:29:07

**US3662049**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:22:50**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-03T11:58:35-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '9c876684-adcd-4ead-a550-506dfce6e50e'	System	03 Mar 2021 16:58:43
User entered 'No (N)'	System	03 Mar 2021 16:58:43

**US3662049**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12e3987f0b28afbd)', Time: '2021-03-03T11:58:39-05:00', User OID: 'PatientReportedOutcome (US3662049)', ODM File OID: '9c876684-adcd-4ead-a550-506dfce6e50e' User entered '03 Mar 2021 11:58:39'	System	03 Mar 2021 16:58:43
	System	03 Mar 2021 16:58:43

**US3662049**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Angela Snyder (b) (4)	30 Nov 2020 17:15:55



**US3662049**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered '27 Nov 2020'	Angela Snyder (b) (4)	30 Nov 2020 17:15:55

**US3662049**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	30 Nov 2020 17:15:55

**US3662049**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered empty.	Angela Snyder (b) (4)	30 Nov 2020 17:15:55

**US3662049**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:46:57
User entered 'Yes (Y)'	Angela Snyder (b) (4)	30 Nov 2020 17:16:01

**US3662049**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:15:06
User entered 'I'	System	30 Nov 2020 17:16:01

**US3662049**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	30 Dec 2020 19:01:59

**US3662049**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '30 Dec 2020'	Angela Snyder (b) (4)	30 Dec 2020 19:01:59

**US3662049**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	30 Dec 2020 19:01:59



**US3662049**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Angela Snyder (b) (4)	30 Dec 2020 19:01:59

**US3662049**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	30 Dec 2020 19:02:05

**US3662049**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User entered 'I'	System	30 Dec 2020 19:02:05

**US3662049**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	28 Jan 2021 11:58:26

**US3662049**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '27 Jan 2021'	Angela Snyder (b) (4)	28 Jan 2021 11:58:26

**US3662049**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	28 Jan 2021 11:58:26

**US3662049**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Angela Snyder (b) (4)	28 Jan 2021 11:58:26

**US3662049**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	28 Jan 2021 11:58:31



**US3662049**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User entered 'I'	System	28 Jan 2021 11:58:31

**US3662049**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	01 Mar 2021 15:01:28

**US3662049**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '26 Feb 2021'	Angela Snyder (b) (4)	01 Mar 2021 15:01:28

**US3662049**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	01 Mar 2021 15:01:28

**US3662049**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Angela Snyder (b) (4)	01 Mar 2021 15:01:28

**US3662049**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	01 Mar 2021 15:01:33

**US3662049**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:48:32
User entered 'I'	System	01 Mar 2021 15:01:33

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Mar 2021 16:26:26
	(b) (4)	



**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '29 Mar 2021'	Angela Snyder (b) (4)	29 Mar 2021 16:26:26
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	29 Mar 2021 16:26:26
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User entered 'VISIT4'	System	29 Mar 2021 16:26:26

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '29 Mar 2021'	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '09:59'	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User entered '29 Mar 2021 09:59'	System	29 Mar 2021 16:27:07

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '97.8' F	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	



**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered 'Other (Other)'	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered 'infrared thermometer'	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '82'	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User entered 'bpm'	System	29 Mar 2021 16:27:07

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '16'	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User entered 'breaths/min'	System	29 Mar 2021 16:27:07

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '142'	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User entered 'mmHg'	System	29 Mar 2021 16:27:07



**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '83'	Angela Snyder (b) (4)	29 Mar 2021 16:27:07
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User entered 'mmHg'	System	29 Mar 2021 16:27:07

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Mar 2021 16:27:17
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:27:17
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Mar 2021 16:27:53
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '29 Mar 2021'	Angela Snyder (b) (4)	29 Mar 2021 16:27:53
	(b) (4)	



**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered '10:05'	Angela Snyder (b) (4)	29 Mar 2021 16:27:53
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User entered '29 Mar 2021 10:05'	System	29 Mar 2021 16:27:53

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:50:27
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Mar 2021 16:27:59
	(b) (4)	

**US3662049**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:52
User entered '1'	System	29 Mar 2021 16:27:59

**US3662049**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:50
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Apr 2021 17:23:35
	(b) (4)	

**US3662049**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:50
	(b) (4)	
User entered '27 Apr 2021'	Angela Snyder (b) (4)	29 Apr 2021 17:23:35
	(b) (4)	

**US3662049**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:23:35

**US3662049**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:50
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:23:35
	(b) (4)	



**US3662049**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:50
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Apr 2021 17:23:39
	(b) (4)	

**US3662049**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 17:23:39

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:53:07
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:22:50**

[Time of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '08:00'	Angela Snyder (b) (4)	19 Apr 2021 16:53:07
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:22:50**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Apr 2021 08:00'	System	19 Apr 2021 16:53:07

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:22:50**

[Type of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:53:07

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:22:50**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Apr 2021 16:53:07
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Day 1 (Day 1)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '31 Mar 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 16:57:43

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Severe (Severe)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:57:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Day 2 (Day 2)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered '1 Apr 2021'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 16:58:58

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:58:58

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Severe (Severe)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:58:58

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:58:58
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Day 3 (Day 3)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '2 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 16:59:56



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Severe (Severe)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 16:59:56
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Day 4 (Day 4)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:00:40

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '3 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 17:00:40

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Severe (Severe)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:00:40
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Day 5 (Day 5)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '4 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 17:01:15

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

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[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	



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**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Severe (Severe)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:15
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Day 6 (Day 6)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '5 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	



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**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 17:01:55

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**Folder: Covid-19 Assessment 09 Apr 2021**

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[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

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**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

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[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

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[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

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[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

**US3662049**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (6)**

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[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Apr 2021**

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[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Severe (Severe)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:01:55
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Day 7 (Day 7)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '6 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 17:02:29



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Severe (Severe)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	



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[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:02:29
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Day 8 (Day 8)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '7 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 17:03:04

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**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered missing code ND - Not Done.	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

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[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

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[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Form: Symptom Log (8)**

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[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	



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**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Generated On: 10 Jun 2021 09:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Form: Symptom Log (8)**

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[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

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**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Severe (Severe)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:04
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Day 9 (Day 9)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	



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**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 17:03:43

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	



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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

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**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Severe (Severe)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:03:43
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Day 10 (Day 10)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '96'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Apr 2021 17:05:32

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '97.7' F	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'None (None)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Not Done (Not Done)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'None (None)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	



**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'None (None)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Severe (Severe)'	(b) (4) Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Not Done (Not Done)'	Angela Snyder (b) (4)	19 Apr 2021 17:05:32
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Visit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 17:22:49
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:22:50**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Apr 2021 17:22:49
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:22:50**

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 17:22:49
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 17:22:49
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:22:50**

[Type of Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Angela Snyder (b) (4)	19 Apr 2021 17:22:49



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Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User closed query 'Type of Test performed is not Other, however, Specify is provided. Please review and reconcile.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	19 Apr 2021 17:23:03
User opened query 'Type of Test performed is not Other, however, Specify is provided. Please review and reconcile.' (Site from System).	Angela Snyder (b) (4)	19 Apr 2021 17:23:03
User entered 'UC Health'	(b) (4)	
	System	19 Apr 2021 17:22:49
	Angela Snyder (b) (4)	19 Apr 2021 17:22:49
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:22:50**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Apr 2021 17:22:49
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:22:50**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 17:23:03
User entered 'UC Health' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Apr 2021 17:23:03
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 17:22:49
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:22:49
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:22:50**

[CLIA Certified?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Apr 2021 17:22:49
	(b) (4)	

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:22:50**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 17:22:49

**US3662049**

**Folder: Covid-19 Assessment 09 Apr 2021**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 17:06:31
	(b) (4)	

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10



**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:10:10
	(b) (4)	

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:10:10
	(b) (4)	

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:10:10
	(b) (4)	

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10



**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:10:10
	(b) (4)	

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:10:10
	(b) (4)	

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:10:10
	(b) (4)	



**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:10:10

**US3662049**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:10:10
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 17:07:07
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:07:07
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:07:07
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	19 Apr 2021 17:07:07

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	



**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

*Date of assessment (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:08

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:08



**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:08

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:08

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:08
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:08

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 17:21:41
	(b) (4)	

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:41
	(b) (4)	



**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:22:50**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Angela Snyder (b) (4) (b) (4)	19 Apr 2021 17:21:48

**US3662049**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:48
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 17:10:19
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:10:19
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:10:19
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	19 Apr 2021 17:10:19

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	



**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:57

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:57

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	



**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:57

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:57

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:21:57
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:21:57

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 17:22:02
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:22:02
	(b) (4)	

**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:22:50**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User entered 'NA (COVID-19 Negative) (NA)'	Angela Snyder (b) (4)	19 Apr 2021 17:22:07



**US3662049**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 17:22:07
	(b) (4)	

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	07 Jan 2021 12:20:18

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '6 Jan 2021'	Angela Snyder (b) (4)	07 Jan 2021 12:20:18

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	07 Jan 2021 12:20:18

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 12:20:18

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '6 Jan 2021'	Angela Snyder (b) (4)	07 Jan 2021 12:20:42

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

[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 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
User entered '0'	Angela Snyder (b) (4)	09 Apr 2021 12:42:44
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:13:54

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	07 Jan 2021 12:20:42



US3662049

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:50

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
User closed query 'Per CDM, per sponsor review: 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) (4), (b) (6)	12 Apr 2021 06:48:04
Query 'Per CDM, per sponsor review: 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 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 12:42:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 12:42:44
User opened query 'Per CDM, per sponsor review: 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)	09 Apr 2021 07:02:51
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:13:54

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '6 Jan 2021'	Angela Snyder (b) (4)	07 Jan 2021 12:20:42

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'mRNA-1273 (mRNA-1273)'	Angela Snyder (b) (4)	07 Jan 2021 12:20:42

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 04:08:26
User entered 'mRNA-1273 (mRNA-1273)'	Angela Snyder (b) (4)	07 Jan 2021 12:20:42
	(b) (4)	

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 04:08:26
User entered 'mRNA-1273 (mRNA-1273)'	Angela Snyder (b) (4)	07 Jan 2021 12:20:42
	(b) (4)	

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	Angela Snyder (b) (4)	07 Jan 2021 12:20:42

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	07 Jan 2021 12:20:42

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:50**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered empty.	System	07 Jan 2021 12:20:42



**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	07 Jan 2021 12:21:03

US3662049

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 06JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:09:41
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 06JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 15:32:28
User entered '6 Jan 2021'	Angela Snyder (b) (4) (b) (4)	07 Jan 2021 12:21:03

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '14:05'	Angela Snyder (b) (4)	07 Jan 2021 12:21:03

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '6 Jan 2021 14:05'	System	07 Jan 2021 12:21:03

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Angela Snyder (b) (4)	07 Jan 2021 12:21:19

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '6 Jan 2021'	Angela Snyder (b) (4)	07 Jan 2021 12:21:19

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '14:00'	Angela Snyder (b) (4)	07 Jan 2021 12:21:19

**US3662049**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:22:50**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:13
User entered '6 Jan 2021 14:00'	System	07 Jan 2021 12:21:19



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:22:50**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
Signature has been broken.	Michelle Saemann (b) (4)	10 Apr 2021 21:44:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Saemann (b) (4)	10 Apr 2021 21:44:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	Angela Snyder (b) (4)	01 Mar 2021 16:54:45

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:11
User entered	System	12 Apr 2021 19:37:59
'USA-US088-2021-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	12 Apr 2021 19:37:59

US3662049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:15:04
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Near syncope - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:30:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:30:26
Data point term sent to Coder	System	19 Apr 2021 14:43:29
DataPoint Un-verified.	System michelle saemann (b) (4)	19 Apr 2021 14:43:09
Coding entries removed.	(b) (4) michelle saemann (b) (4)	19 Apr 2021 14:43:09
Signature has been broken.	(b) (4) michelle saemann (b) (4)	19 Apr 2021 14:43:09
User entered 'hypotension with near syncope' reason for change: Data Entry Error	(b) (4) michelle saemann (b) (4)	19 Apr 2021 14:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:13:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Orthopnoea, LLT: Orthopnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Apr 2021 21:51:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Apr 2021 21:51:42
Data point term sent to Coder	System	10 Apr 2021 21:51:22
User entered 'orthopnea'	michelle saemann (b) (4) (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'No (N)'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:15:07
Signature has been broken.	Angela Snyder (b) (4)	19 Apr 2021 16:34:57
User entered '9 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Apr 2021 16:34:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Un-verified.	michelle saemann (b) (4)	14 Apr 2021 16:10:56
User entered '02 Apr 2021' reason for change: Data Entry Error	michelle saemann (b) (4)	14 Apr 2021 16:10:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '09 Apr 2021'	michelle saemann (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered empty.	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:15:10
DataPoint Un-verified.	Michelle Saemann (b) (4)	19 Apr 2021 14:43:09
Signature has been broken.	Michelle Saemann (b) (4)	19 Apr 2021 14:43:09
User entered 'No (N)' reason for change: Data Entry Error	Michelle Saemann (b) (4)	19 Apr 2021 14:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'Yes (Y)'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:15:12
User entered '9 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Apr 2021 16:34:57
DataPoint Un-verified.	(b) (4)	
	michelle saemann (b) (4)	19 Apr 2021 14:43:09
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	19 Apr 2021 14:43:09
	(b) (4)	
User entered '10 Apr 2021' reason for change: Data Entry Error	michelle saemann (b) (4)	19 Apr 2021 14:43:09
User signature succeeded.	(b) (4)	
	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered empty.	(b) (4)	
	michelle saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered empty.	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	michelle saemann (b) (4) (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '0'	michelle saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '0'	michelle saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'I'	michelle saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '09 Apr 2021'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '10 Apr 2021'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'No (N)'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered empty.	michelle saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '0'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '0'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '0'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4) (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4) (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'Not Applicable (NOT APPLICABLE)'	michelle saemann (b) (4) (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[None](#)

Audit	User	Time (GMT)
Signature has been broken.	Angela Snyder (b) (4)	19 Apr 2021 16:40:03
	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '0'	michelle saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:27
DataPoint Un-verified.	Michelle Saemann (b) (4)	19 Apr 2021 14:43:09
Signature has been broken.	Michelle Saemann (b) (4)	19 Apr 2021 14:43:09
User entered '1' reason for change: Data Entry Error	Michelle Saemann (b) (4)	19 Apr 2021 14:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered '0'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'I'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:15:16
DataPoint Un-verified.	Michelle Saemann (b) (4)	19 Apr 2021 14:43:09
Signature has been broken.	Michelle Saemann (b) (4)	19 Apr 2021 14:43:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Michelle Saemann (b) (4)	19 Apr 2021 14:43:09
Data Entry Error	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Michelle Saemann (b) (4)	10 Apr 2021 21:50:28



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered empty.	michelle saemann (b) (4)	10 Apr 2021 21:50:28
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query - Please provide the diagnostic tests dates for CBC, LDH, CK, O and P, enteric pathogen panel, and clostridioides difficile' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:09:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:26

US3662049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:50

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT WITH 3 WEEK HISTORY OF WORSENING DYSPNEA WITH EXERTION AND RECENT PROGRESSION TO SHORTNESS OF BREATH WHEN LYING DOWN. BEDSIDE ECHO DEMONSTRATED A CONCERN FOR RIGHT HEART STRAIN; HOWEVER CTPA NEGATIVE FOR PE. CHEST XRAY WITH NO ACUTE CARDIOPULMONARY ABNORMALITIES. PATIENT HAS RECEIVED BOTH DOSE OF COVID VACCINE. CBC, LDH, AND CK WITHIN NORMAL LIMITS. ANA AND ALDOLASE STUDIES PENDING AT DISCHARGE. FORMAL ECHO TO BE OBTAINED OUTPATIENT AS SOON AS IT CAN BE SCHEDULED. HYPOTENSION, LIGHTHEADEDNESS. PATIENT RECORDED HYPOTENSION AT HOME AND WAS ENCOURAGED TO COME INTO THE HOSPITAL. NORMO/HYPERTENSIVE IN THE EMERGENCY DEPARTMENT. PATIENT'S HISTORY OF LIGHTHEADEDNESS IN ACCORDANCE WITH ORTHOSTASIS. THOUGHT TO BE ASSOCIATED WITH THE INCREASED, LOOSE BOWEL MOVEMENTS AS DESCRIBED BELOW. PATIENT TREATED WITH IV FLUIDS WITH IMPROVEMENT OF SYMPTOMS. HE WAS NOT ORTHOSTATIC. DOXAZOSIN WAS DISCONTINUED DUE TO THIS CONCERN.  DIARRHEA. ENDORSES A FIVE DAY HISTORY OF 7-8 LOOSE STOOLS A DAY WITHOUT ABDOMINAL PAIN, MELENA OR HEMATOCHYZIA. ETIOLOGY UNCLEAR. O&P, ENTERIC PATHOGEN PANEL, C DIF PENDING AT DISCHARGE. WILL UPDATE AE AND PROCEDURE LOG. 4/19/21 AFTER REVIEW OF HOSPITAL RECORDS AND F/U WITH PI, SAE TERM UPDATED TO HYPOTENSION WITH NEAR SYNCOPE PER PI INSTRUCTION. Participant took lisinopril and doxazosin together and PI feels this is what caused the hypotension with near syncope.'	michelle saemann (b) (4)	(b) (4) 19 Apr 2021 14:45:21
reason for change: Data Entry Error		

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	michelle saemann (b) (4)	19 Apr 2021 14:43:09
	(b) (4)	
Signature has been broken.	michelle saemann (b) (4)	19 Apr 2021 14:43:09
	(b) (4)	

US3662049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:50

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT WITH 3 WEEK HISTORY OF WORSENING DYSPNEA WITH EXERTION AND RECENT PROGRESSION TO SHORTNESS OF BREATH WHEN LYING DOWN. BEDSIDE ECHO DEMONSTRATED A CONCERN FOR RIGHT HEART STRAIN; HOWEVER CTPA NEGATIVE FOR PE. CHEST XRAY WITH NO ACUTE CARDIOPULMONARY ABNORMALITIES. PATIENT HAS RECEIVED BOTH DOSE OF COVID VACCINE. CBC, LDH, AND CK WITHIN NORMAL LIMITS. ANA AND ALDOLASE STUDIES PENDING AT DISCHARGE. FORMAL ECHO TO BE OBTAINED OUTPATIENT AS SOON AS IT CAN BE SCHEDULED. HYPOTENSION, LIGHTHEADEDNESS. PATIENT RECORDED HYPOTENSION AT HOME AND WAS ENCOURAGED TO COME INTO THE HOSPITAL. NORMO/HYPERTENSIVE IN THE EMERGENCY DEPARTMENT. PATIENT'S HISTORY OF LIGHTHEADEDNESS IN ACCORDANCE WITH ORTHOSTASIS. THOUGHT TO BE ASSOCIATED WITH THE INCREASED, LOOSE BOWEL MOVEMENTS AS DESCRIBED BELOW. PATIENT TREATED WITH IV FLUIDS WITH IMPROVEMENT OF SYMPTOMS. HE WAS NOT ORTHOSTATIC. DOXAZOSIN WAS DISCONTINUED DUE TO THIS CONCERN.  DIARRHEA. ENDORSES A FIVE DAY HISTORY OF 7-8 LOOSE STOOLS A DAY WITHOUT ABDOMINAL PAIN, MELENA OR HEMATOCHYZIA. ETIOLOGY UNCLEAR. O&P, ENTERIC PATHOGEN PANEL, C DIF PENDING AT DISCHARGE. WILL UPDATE AE AND PROCEDURE LOG. 4/19/21 After review of hospital records and f/u with PI, SAE term updated to hypotension with near syncope per PI instruction.' reason for change: Data Entry Error	michelle saemann (b) (4)	(b) (4) 19 Apr 2021 14:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	(b) (4) 16 Apr 2021 19:03:15

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3662049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:50

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:21
User entered 'Patient with 3 week history of worsening dyspnea with exertion and recent progression to shortness of breath when lying down. Bedside echo demonstrated a concern for right heart strain; however CTPA negative for PE. Chest xray with no acute cardiopulmonary abnormalities. Patient has received both dose of COVID vaccine. CBC, LDH, and CK within normal limits. ANA and aldolase studies pending at discharge. Formal echo to be obtained outpatient as soon as it can be scheduled. Hypotension, lightheadedness. Patient recorded hypotension at home and was encouraged to come into the hospital. Normo/hypertensive in the emergency department. Patient's history of lightheadedness in accordance with orthostasis. Thought to be associated with the increased, loose bowel movements as described below. Patient treated with IV fluids with improvement of symptoms. He was not orthostatic. Doxazosin was discontinued due to this concern. Diarrhea. Endorses a five day history of 7-8 loose stools a day without abdominal pain, melena or hematochezia. Etiology unclear. O&P, enteric pathogen panel, c dif pending at discharge. Will update AE and procedure log.'	michelle saemann (b) (4)	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Apr 2021 21:50:28

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Apr 2021 21:50:28



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Apr 2021 21:50:28

US3662049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 21:40:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 21:40:43
Data point term sent to Coder	System	19 Apr 2021 16:37:05
User entered 'acute renal injury'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '9 Apr 2021'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:36:03



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '10 Apr 2021'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'I'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:16:56
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 16:36:03

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 16:20:14
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 12:57:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Orthopnoea, LLT: Orthopnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 16:38:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 16:38:52
Data point term sent to Coder	System	19 Apr 2021 16:38:06
User entered 'orthopnea'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered '2 Apr 2021'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:56:23 19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered 'I'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

US3662049

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User closed query 'PV Query: Narrative mentions the discontinuation of doxazosin. Was the subject taking doxazosin at the time of the event as concomitant medication or treatment?' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:19:49
Query 'PV Query: Narrative mentions the discontinuation of doxazosin. Was the subject taking doxazosin at the time of the event as concomitant medication or treatment?' answered with 'no. doxazosin not related to orthopnea. ' (Site from Safety).	michelle saemann (b) (4)	20 Apr 2021 17:42:35
User opened query 'PV Query: Narrative mentions the discontinuation of doxazosin. Was the subject taking doxazosin at the time of the event as concomitant medication or treatment?' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 12:57:45
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:37:12



US3662049

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User closed query 'PV Query: Please provide the results of the O and P, enteric pathogen panel, ANA, and aldolase, and clostridioides difficile' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:19:53
User closed query 'PV Query - Please provide the diagnostic tests dates for CTPA, Chest X-ray, CBC, LDH, CK, O and P, enteric pathogen panel, and clostridioides difficile' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:19:51
Query 'PV Query: Please provide the results of the O and P, enteric pathogen panel, ANA, and aldolase, and clostridioides difficile' answered with 'O&P negative, Crypto negative, Giardia negative, enteric pathogen negative, C-Diff negative, ANA negative, Aldolase 5.3 (range 3.3-10.3)' (Site from Safety).	michelle saemann (b) (4)	20 Apr 2021 17:47:15
Query 'PV Query - Please provide the diagnostic tests dates for CTPA, Chest X-ray, CBC, LDH, CK, O and P, enteric pathogen panel, and clostridioides difficile' answered with 'labs are not con procedures. See con procedure folder' (Site from Safety).	michelle saemann (b) (4)	20 Apr 2021 17:43:56
User opened query 'PV Query: Please provide the results of the O and P, enteric pathogen panel, ANA, and aldolase, and clostridioides difficile' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 12:57:31
User opened query 'PV Query - Please provide the diagnostic tests dates for CTPA, Chest X-ray, CBC, LDH, CK, O and P, enteric pathogen panel, and clostridioides difficile' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 12:56:51
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 12:57:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:37:12

US3662049

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:50

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:17:50
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:19:54
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'See COVID contact folder. Entered there per teams instructions. ' (Site from Safety).	michelle saemann (b) (4)	20 Apr 2021 17:44:31
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 12:56:01
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 16:37:12

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 16:37:12

US3662049

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:21:05
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 16:39:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 16:39:30
Data point term sent to Coder	System	19 Apr 2021 16:39:07
User entered 'diarrhea'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

US3662049

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:57:33
User closed query 'Per source this event is an MAAE. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:57:27
Query 'Per source this event is an MAAE. Please verify and update as needed. ' answered with 'Data updated' (Site from CRA).	Angela Snyder (b) (4) (b) (4)	22 Apr 2021 11:46:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	22 Apr 2021 11:45:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User opened query 'Per source this event is an MAAE. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:20:34
Query 'Per source this event is an MAAE. Please verify and update as needed. ' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:20:00
User opened query 'Per source this event is an MAAE. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:18:44
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:21:01
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:21:03
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

**Start date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:57:32
User closed query 'Per source start date is 31Mar2021. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:57:30
Query 'Per source start date is 31Mar2021. Please verify and update as needed. ' answered with 'Data updated' (Site from CRA).	Angela Snyder (b) (4)	22 Apr 2021 11:46:19
User entered '31 Mar 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	22 Apr 2021 11:45:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User opened query 'Per source start date is 31Mar2021. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:21:00
User entered '24 Mar 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:21:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:21:10
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:57:40
User closed query 'Per source stop date is 10Apr2021. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:57:37
Query 'Per source stop date is 10Apr2021. Please verify and update as needed. ' answered with 'Data updated' (Site from CRA).	Angela Snyder (b) (4)	22 Apr 2021 11:46:36
User entered '10 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	22 Apr 2021 11:45:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User opened query 'Per source stop date is 10Apr2021. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:21:30
User entered '8 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:22:54
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:38:08

US3662049

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:50

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:57:45
User closed query 'Per source grade is 3. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:57:42
Query 'Per source grade is 3. Please verify and update as needed. ' answered with 'Data updated' (Site from CRA).	Angela Snyder (b) (4)	22 Apr 2021 11:46:53
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 11:45:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User opened query 'Per source grade is 3. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:22:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angela Snyder (b) (4)	19 Apr 2021 16:38:08
	(b) (4)	

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:22:52
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08



**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered '0' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Apr 2021 16:38:20
User entered '1'	Angela Snyder (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered '1' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Apr 2021 16:38:20
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:27
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 16:38:08

**US3662049**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 11:45:40
User entered '0'	System	19 Apr 2021 16:38:08



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:22:50**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:27:56

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Sep 2020 05:45:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:45:39
Data point term sent to Coder	System	12 Sep 2020 16:31:15
User entered 'OMEPRAZOLE'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:30:41

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add this medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 09:31:30
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add this medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'done' (Site from DM).	michelle saemann (b) (4) (b) (4)	17 Oct 2020 18:07:04
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add this medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:02:14
User entered 'BURNING IN EPIGASTRUM'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:30:41

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '40'	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:30:41

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '22 Feb 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:30:41

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:30:41
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:30:41



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:30:41

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:30:41

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 16:30:41

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Sep 2020 06:01:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 06:01:43
Data point term sent to Coder	System	12 Sep 2020 16:32:16
User entered 'TRAZODONE HCI'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'DEPRESSION'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '50'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'mg (mg)'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'once daily (QD)'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '21 Feb 2020'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
Signature has been broken.	Angela Snyder (b) (4)	19 Apr 2021 16:26:21
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Apr 2021 16:26:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
Signature has been broken.	Angela Snyder (b) (4)	19 Apr 2021 16:26:21
User entered '3 Feb 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Apr 2021 16:26:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User entered '1'	System	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User entered '1'	System	12 Sep 2020 16:31:31

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User entered '804 (804)'	System	12 Sep 2020 16:31:31

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Sep 2020 04:27:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 04:27:39
Data point term sent to Coder	System	12 Sep 2020 16:33:16
User entered 'FLOMAX'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'OVERACTIVE BLADDER'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '.8'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'mg (mg)'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'once daily (QD)'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '29 Aug 2019'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
Signature has been broken.	Michelle Saemann (b) (4)	22 Apr 2021 12:14:08
User entered 'No (N)' reason for change: Data Entry Error	Michelle Saemann (b) (4)	22 Apr 2021 12:14:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
Signature has been broken.	Michelle Saemann (b) (4)	22 Apr 2021 12:14:08
User entered '04 Mar 2021' reason for change: Data Entry Error	Michelle Saemann (b) (4)	22 Apr 2021 12:14:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User entered '1'	System	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User entered '1'	System	12 Sep 2020 16:32:39

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User entered '804 (804)'	System	12 Sep 2020 16:32:39

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN SODIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Sep 2020 16:35:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:35:36
Data point term sent to Coder	System	12 Sep 2020 16:34:17
User entered 'PRAVASTATIN SODIUM'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:33:42



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:33:42
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'HYPERLIPIDEMIA'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:33:42

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '40'	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:33:42
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:33:42

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:33:42
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:33:42

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:33:42
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:33:42



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:33:42
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '06 Aug 2019'	Brenda Miller (b) (4)	12 Sep 2020 16:33:42
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:33:42
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:33:42
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:33:42
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:33:42

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:33:42

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:33:42



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 16:33:42

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Sep 2020 16:36:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:36:37
Data point term sent to Coder	System	12 Sep 2020 16:35:18
User entered 'ASCORBIC ACID'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:34:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Brenda Miller (b) (4)	28 Oct 2020 23:17:32
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:34:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'SUPPLEMENT'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:34:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '500'	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	14 Sep 2020 14:04:39
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	12 Sep 2020 16:34:38
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:34:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4)	14 Sep 2020 14:04:39
	(b) (4)	
User entered 'O'	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'once daily (QD)'	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '01 Jul 2019'	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:34:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:34:38



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:34:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:34:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 16:34:38

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Sep 2020 05:43:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:43:40
Data point term sent to Coder	System	12 Sep 2020 16:37:22
User entered 'MULTI VITAMINS'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:36:32

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Brenda Miller (b) (4)	28 Oct 2020 23:17:53
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:36:32
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'SUPPLEMENT'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:36:32

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '1'	Brenda Miller (b) (4)	12 Sep 2020 16:36:32
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'tablet (TABLET)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:36:32



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:36:32
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:36:32

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:36:32
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:36:32

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:36:32
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '01 Jul 2019'	Brenda Miller (b) (4)	12 Sep 2020 16:36:32
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:36:32
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:36:32
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:36:32
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:36:32

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:36:32

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:36:32

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 16:36:32

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
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: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Sep 2020 16:39:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:39:40
Data point term sent to Coder	System	12 Sep 2020 16:38:22
User entered 'VITAMIN D'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:37:28

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	28 Oct 2020 23:18:22
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'SUPPLEMENT'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:37:28



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '2000'	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'IU (IU)'	Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:37:28

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:37:28

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '28 Jul 2019'	Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:37:28
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:37:28

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:37:28

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:37:28

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 16:37:28

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE, PRODUCTSYNONYM: ANDROGEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 09:26:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 09:26:45
Data point term sent to Coder Coding entries removed.	System michelle saemann (b) (4)	16 Oct 2020 20:03:38 16 Oct 2020 20:02:55
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE, PRODUCTSYNONYM: ANDROGEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 16:40:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 16:40:40
Data point term sent to Coder User entered 'ANDROGEL'	System Brenda Miller (b) (4)	12 Sep 2020 16:39:24 12 Sep 2020 16:38:38



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add this medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 09:32:00
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add this medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'done' (Site from DM).	michelle saemann (b) (4) (b) (4)	16 Oct 2020 20:03:00
User entered 'hypogonadism' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	16 Oct 2020 20:02:55
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add this medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:02:59
User entered 'LOW TESTOSTERONE'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:38:38

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM). Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' answered with 'done' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 09:32:06
User entered '50' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	16 Oct 2020 20:08:41
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM). User entered '1'	michelle saemann (b) (4) (b) (4), (b) (6)	16 Oct 2020 20:08:26 09 Oct 2020 14:03:22
	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:38:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	michelle saemann (b) (4)	16 Oct 2020 20:08:26
	(b) (4)	
User entered 'Other (OTHER)'	Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	michelle saemann (b) (4)	16 Oct 2020 20:08:26
	(b) (4)	
User entered 'PERCENT'	Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:38:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'Topical (TOPICAL)'	Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '21 Jul 2015'	Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:38:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:38:38

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:38:38



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 16:38:38

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:50

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Sep 2020 16:41:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:41:40
Data point term sent to Coder User entered 'LISINOPRIL'	System Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:40:24 12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'HYPERTENSION'	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '20'	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'mg (mg)'	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'once daily (QD)'	Brenda Miller (b) (4)	12 Sep 2020 16:39:33



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '16 Oct 2014'	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '0'	Brenda Miller (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:42
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:24:18
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:24:18
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:42
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:24:18
User entered '14 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:24:18
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 21:45:50
User entered empty.	Brenda Miller (b) (4) (b) (4)	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:39:33



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 16:39:33

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Sep 2020 16:39:33

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: BIKTARVY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 20:12:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 20:12:47
Data point term sent to Coder	System	14 Sep 2020 20:11:55
User entered 'BIKTARVY'	Brenda Miller (b) (4)	14 Sep 2020 20:11:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	14 Sep 2020 20:11:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'HIV'	(b) (4) Brenda Miller (b) (4) (b) (4)	14 Sep 2020 20:11:05

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User closed query 'Per DM CLR: Please update the CM dosage to include all of the medication dosages in this combination medication (i.e.: 50/200/25). Please review and update the CM page as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 09:32:16
Query 'Per DM CLR: Please update the CM dosage to include all of the medication dosages in this combination medication (i.e.: 50/200/25). Please review and update the CM page as appropriate. ' answered with 'done' (Site from DM).	michelle saemann (b) (4) (b) (4)	16 Oct 2020 20:02:06
User entered '50/200/25' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	16 Oct 2020 20:02:01
User opened query 'Per DM CLR: Please update the CM dosage to include all of the medication dosages in this combination medication (i.e.: 50/200/25). Please review and update the CM page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:07:14
User entered '275'	Brenda Miller (b) (4) (b) (4)	14 Sep 2020 20:11:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	14 Sep 2020 20:11:05



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	14 Sep 2020 20:11:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	14 Sep 2020 20:11:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	14 Sep 2020 20:11:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4) (b) (4)	14 Sep 2020 20:11:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4)	14 Sep 2020 20:11:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
	(b) (4)	
User entered '31 Aug 2019'	Brenda Miller (b) (4)	14 Sep 2020 20:11:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered '0'	(b) (4) Brenda Miller (b) (4) (b) (4)	14 Sep 2020 20:11:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	14 Sep 2020 20:11:05



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered empty.	(b) (4) Brenda Miller (b) (4) (b) (4)	14 Sep 2020 20:11:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	14 Sep 2020 20:11:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:11:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 20:11:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 20:11:05

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE HYDROCHLORIDE, PRODUCTSYNONYM: TRAZODONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:14:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:14:52
Data point term sent to Coder Coding entries removed.	System michelle saemann (b) (4)	22 Apr 2021 12:13:30 22 Apr 2021 12:13:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE HYDROCHLORIDE, PRODUCTSYNONYM: TRAZODONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 16:29:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 16:29:00
Data point term sent to Coder User entered 'trazodone hcl'	System Angela Snyder (b) (4)	19 Apr 2021 16:27:55 19 Apr 2021 16:27:12

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'depressive disorder' reason for change:	Data Entry Error	
	Data Entry Error	
User entered 'depression'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '100'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '4 Feb 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 16:27:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:27:12

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:27:12

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 16:27:12

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DOXAZOSIN MESILATE, PRODUCTSYNONYM: DOXAZOSIN MESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:53:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:53:13
Data point term sent to Coder	System	19 Apr 2021 16:29:56
User entered 'doxazosin mesylate'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'overactive bladder'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '4'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '5 Mar 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 16:29:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:29:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:29:29



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 16:29:29

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:16
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 16:32:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 16:32:37
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 16:31:58
User entered 'omnipaque'	Angela Snyder (b) (4)	19 Apr 2021 16:31:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered 'procedure'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered '255'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered '9 Apr 2021'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:31:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:31:29
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:16
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:31:29



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:31:29

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:31:29

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DOXAZOSIN MESILATE, PRODUCTSYNONYM: DOXAZOSIN MESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:53:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:53:13
Data point term sent to Coder	System	19 Apr 2021 16:32:59
User entered 'doxazosin mesylate'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:32:47

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered 'No (N)'	Angela Snyder (b) (4)	19 Apr 2021 16:32:47
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered 'hypertension/overactive bladder'	Angela Snyder (b) (4)	19 Apr 2021 16:32:47
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered '8'	Angela Snyder (b) (4)	19 Apr 2021 16:32:47
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:32:47



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:32:47
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered 'once daily (QD)'	Angela Snyder (b) (4)	19 Apr 2021 16:32:47
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:32:47

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:32:47

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:32:47

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered '15 Apr 2021'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:32:47

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:32:47
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:32:47



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:32:47

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:49
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:32:47

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:32:47

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:32:47

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 16:32:47

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:03:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:03:37
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 16:43:22
User entered 'magnesium sulfate'	Angela Snyder (b) (4)	19 Apr 2021 16:42:21
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered 'diarrhea'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered '4'	Angela Snyder (b) (4)	19 Apr 2021 16:42:21
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered 'g (g)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered '10 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:42:21
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:42:21
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered '10 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:42:21
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:52
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:42:21

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:42:21

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:06:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:06:12
Data point term sent to Coder	System	19 Apr 2021 16:44:23
User entered 'potassium chloride'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered 'diarrhea'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered '40'	Angela Snyder (b) (4)	19 Apr 2021 16:44:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	19 Apr 2021 16:44:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered 'meq'	Angela Snyder (b) (4)	19 Apr 2021 16:44:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered '10 Apr 2021'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:44:05
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered '10 Apr 2021'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:58
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:44:05

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:44:05



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:44:05

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:01:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:01:06
Data point term sent to Coder	System	19 Apr 2021 16:46:29
User entered 'heparin'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered 'blood clot prevention'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered '5000'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered 'IU (IU)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered 'once daily (QD)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered 'Subcutaneous (SUBCUTANEOUS)'	Angela Snyder (b) (4)	19 Apr 2021 16:45:58
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered empty.	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered '9 Apr 2021'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered '0'	Angela Snyder (b) (4)	19 Apr 2021 16:45:58
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered '10 Apr 2021'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:44:55
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:45:58



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:45:58

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 16:45:58

US3662049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:19:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 12:19:51
Data point term sent to Coder	System	22 Apr 2021 12:18:31
User entered 'lactated ringers'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'hypotension'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '100'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'MI/hr'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	



**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered '10 Apr 2021'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	22 Apr 2021 12:18:23
	(b) (4)	

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 12:18:23

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 12:18:23

**US3662049**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 12:18:23

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:22:50**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
Signature has been broken.	Angela Snyder (b) (4)	19 Apr 2021 16:47:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Apr 2021 16:47:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:45:50
User entered 'No (N)'	Brenda Miller (b) (4)	12 Sep 2020 16:39:52

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:22:50**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:31
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:47:20
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:31
User entered 'ecg'	Angela Snyder (b) (4)	19 Apr 2021 16:47:20
	(b) (4)	



**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:31
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	19 Apr 2021 16:47:20
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:22:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:31
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:47:20
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:22:50**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:38
User entered '14 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:47:46
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:38
User entered 'echo 2d complete'	Angela Snyder (b) (4)	19 Apr 2021 16:47:46
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:38
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	19 Apr 2021 16:47:46
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:22:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:38
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:47:46
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:22:50**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:47
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:48:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:47
User entered 'cxr pa lateral'	Angela Snyder (b) (4)	19 Apr 2021 16:48:12
	(b) (4)	



**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:47
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	19 Apr 2021 16:48:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:22:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:47
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:48:12
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:22:50**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:54
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:48:57
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:54
User entered 'bedside focused transthoracic echocardiogram'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:48:57

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:54
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:48:57

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:22:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:54
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:48:57
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:22:50**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:58
User entered '9 Apr 2021'	Angela Snyder (b) (4)	19 Apr 2021 16:49:49
	(b) (4)	

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:58
User entered 'ct pulmonary angiography'	Angela Snyder (b) (4)	19 Apr 2021 16:49:49
	(b) (4)	



**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:58
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4) (b) (4)	19 Apr 2021 16:49:49

**US3662049**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:22:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:58
User entered empty.	Angela Snyder (b) (4)	19 Apr 2021 16:49:49
	(b) (4)	

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:33
User entered		
'USA-US088-2021-MRNA-1273-P301000011'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Carl'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Fichtenbaum'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '231 Albert Sabin Way'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Cincinnati'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '45267'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:08:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
User entered 'US'	System	12 Apr 2021 19:39:43



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Apr 2021 16:21:01
User entered '3'	System	20 Apr 2021 17:09:08
User entered '2'	System	15 Apr 2021 13:02:48
User entered '1'	System	12 Apr 2021 19:39:43

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:33
User entered		
'USA-US088-2021-MRNA-1273-P301000011'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Carl'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Fichtenbaum'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '231 Albert Sabin Way'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Cincinnati'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '45267'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:08:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
User entered 'US'	System	12 Apr 2021 19:39:43

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Apr 2021 16:21:01
User entered '3'	System	20 Apr 2021 17:09:08
User entered '2'	System	15 Apr 2021 13:02:48
User entered '1'	System	12 Apr 2021 19:39:43



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
User entered '12/Apr/2021 15:39'	System	12 Apr 2021 19:39:43

US3662049

Folder: SAE USA-US088-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:08:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:08:36
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 19:39:43

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:33
User entered		
'USA-US088-2021-MRNA-1273-P301000011'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Carl'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Fichtenbaum'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '231 Albert Sabin Way'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Cincinnati'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '45267'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:08:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
User entered 'US'	System	12 Apr 2021 19:39:43



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Apr 2021 16:21:01
User entered '3'	System	20 Apr 2021 17:09:08
User entered '2'	System	15 Apr 2021 13:02:48
User entered '1'	System	12 Apr 2021 19:39:43

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
User entered '15/Apr/2021 06:02'	(b) (4) System	15 Apr 2021 13:02:48

US3662049

Folder: SAE USA-US088-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:14:39
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:08:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:02:48

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:33
User entered 'USA-US088-2021-MRNA-1273-P301000011'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Carl'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Fichtenbaum'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '231 Albert Sabin Way'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Cincinnati'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '45267'	System	12 Apr 2021 19:37:59



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:08:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
User entered 'US'	System	12 Apr 2021 19:39:43

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Apr 2021 16:21:01
User entered '3'	System	20 Apr 2021 17:09:08
User entered '2'	System	15 Apr 2021 13:02:48
User entered '1'	System	12 Apr 2021 19:39:43

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:14:39
User entered '20/Apr/2021 17:09'	System	20 Apr 2021 17:09:08

US3662049

Folder: SAE USA-US088-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:14:39
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 16:20:37
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 17:09:08

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:33
User entered		
'USA-US088-2021-MRNA-1273-P301000011'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Yes (Y)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'No (N)'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Carl'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Fichtenbaum'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '231 Albert Sabin Way'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered 'Cincinnati'	System	12 Apr 2021 19:37:59



**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:08:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 19:39:36
User entered '45267'	System	12 Apr 2021 19:37:59

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:08:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:03:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:08:36
User entered 'US'	System	12 Apr 2021 19:39:43

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Apr 2021 16:21:01
User entered '3'	System	20 Apr 2021 17:09:08
User entered '2'	System	15 Apr 2021 13:02:48
User entered '1'	System	12 Apr 2021 19:39:43

**US3662049**

**Folder: SAE USA-US088-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:14:39
User entered '21/Apr/2021 12:21'	System	21 Apr 2021 16:21:01

US3662049

Folder: SAE USA-US088-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:14:39
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 16:21:01