

US3552053 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:08:15

All time stamps listed in this document are displayed in GMT

US3552053

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

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Participant ID

US3552053

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

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US3552053

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3552053

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 17:36:43

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

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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) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

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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) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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

US3552053

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	CHRONIC RIGHT UVEITIS
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	LEFT MENISCUS TEAR
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	LEFT MENISCUS ARTHROSCOPIC REPAIR
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Mar 2021 16:50:55

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Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN AUG 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 1996
Stop date completely unknown	False
Start Month and Year (derived)	AUG 1996
Start Year (derived)	1996
Stop Month and Year (derived)	AUG 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	AUG 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	BUNIONECTOMY LEFT FIRST METATARSAL AND 5TH METATARSAL
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	BUNIONECTOMY RIGHT FIRST METATARSAL AND 5TH METATARSAL
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	BUNIONS: LEFT FIRST METATARSAL AND 5TH METATARSAL, RIGHT FIRST METATARSAL AND 5TH METATARSAL
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	MITRAL VALVE PROLAPSE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	IRRITABLE BOWEL DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	NAUSEA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Condition	CARDIAC ARRYTHMIA - PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:42
Height (xxx.x)	67 in
Weight (xxx.x)	170.6 lb
BMI (xxx.x)	26.77561 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) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Date of assessment (*dd MMM yyyy*) 17 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN AUG 1996

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:36:43

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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**

BABY SITTING  
GRANDCHILDREN TWICE A  
WEEK, WEEKLY DINNERS WITH  
CHILDREN, WEEKLY GROCERY  
STORE TRIPS

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

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:36:43

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No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

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

What was the participant's randomization number? 186595

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

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) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:42
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 14:06
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 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)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

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) 21 Feb 2021 17:36:43

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Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 AUG 2020

What was the treatment time? (00:00-23:59) 13:36 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 13:36

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 AUG 2020
Collection time (00:00-23:59)	12:50 (24 HR)
Collection date and time (derived)	17 AUG 2020 12:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:54	17 AUG 2020 12:54
Nasopharyngeal Swab 2	No		

US3552053

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**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

96.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	17 AUG 2020 14:08
PC Open Date & Time	17 AUG 2020 13:56
PC Close Date & Time	17 AUG 2020 16:26

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**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 96.3 °F

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

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

PC Time Stamp	17 AUG 2020 18:17
PC Open Date & Time	17 AUG 2020 17:21
PC Close Date & Time	18 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 14:46

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**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

19 AUG 2020 20:03

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 18:14

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59



US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**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

97.1 °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

21 AUG 2020 18:46

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 21:04

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 20:09

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 14:08

PC Open Date & Time

17 AUG 2020 13:56

PC Close Date & Time

17 AUG 2020 16:26

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 18:17

PC Open Date & Time

17 AUG 2020 17:21

PC Close Date & Time

18 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

4

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

18 AUG 2020 14:48

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 20:03

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 18:14

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59



US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 18:46

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 21:05

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 20:10

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**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 ☐

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 14:09
PC Open Date & Time	17 AUG 2020 13:56
PC Close Date & Time	17 AUG 2020 16:26

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**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 ☐

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 18:18
PC Open Date & Time	17 AUG 2020 17:21
PC Close Date & Time	18 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 14:48
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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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US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:04
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 18:15
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 18:46
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 21:05
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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)

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 20:10
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3552053

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552053

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552053

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3552053

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:37:06

Generated On: 10 Jun 2021 08:08:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT2

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:37:06

Generated On: 10 Jun 2021 08:08:15

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)	14 SEP 2020
Time of assessment (00:00-23:59)	12:02 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:02
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:37:06

Generated On: 10 Jun 2021 08:08:15

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)	14 SEP 2020
Time of assessment (00:00-23:59)	13:33 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:33
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3552053

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:37:06

Generated On: 10 Jun 2021 08:08:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 13:03 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 13:03

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

US3552053

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 SEP 2020
Collection time (00:00-23:59)	12:29 (24 HR)
Collection date and time (derived)	14 SEP 2020 12:29

US3552053

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:33	14 SEP 2020 12:33
Nasopharyngeal Swab 2	No		



US3552053

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 13:31

PC Open Date & Time

14 SEP 2020 13:23

PC Close Date & Time

14 SEP 2020 15:53

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	14 SEP 2020 18:51
PC Open Date & Time	14 SEP 2020 16:48
PC Close Date & Time	15 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**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

101.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 12:08

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 13:03

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:49

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 13:37

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 08:19

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59



US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 08:51

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**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

14 SEP 2020 13:32

PC Open Date & Time

14 SEP 2020 13:23

PC Close Date & Time

14 SEP 2020 15:53

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**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

14 SEP 2020 18:51

PC Open Date & Time

14 SEP 2020 16:48

PC Close Date & Time

15 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**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

15 SEP 2020 12:08

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**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

16 SEP 2020 13:04

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**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

17 SEP 2020 12:49

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**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

18 SEP 2020 13:38

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 08:19

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59



US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 08:51

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**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 ☐

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 13:32
PC Open Date & Time	14 SEP 2020 13:23
PC Close Date & Time	14 SEP 2020 15:53

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**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 ☐

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 18:51
PC Open Date & Time	14 SEP 2020 16:48
PC Close Date & Time	15 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☒

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 12:09
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 13:04
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

	Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 12:50
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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 ☐

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

		Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 13:38	
PC Open Date & Time	18 SEP 2020 12:00	
PC Close Date & Time	19 SEP 2020 11:59	

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 08:19
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

119 of 2384

EAB) (1725)



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 08:52
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3552053

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552053

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552053

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552053

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:37:06

Generated On: 10 Jun 2021 08:08:15

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



US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:37:06

Generated On: 10 Jun 2021 08:08:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:36
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552053

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:37:06

Generated On: 10 Jun 2021 08:08:15

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.*

US3552053

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:37:06

Generated On: 10 Jun 2021 08:08:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 OCT 2020
Collection time (00:00-23:59)	12:05 (24 HR)
Collection date and time (derived)	12 OCT 2020 12:05

US3552053

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:37:06

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 16:56:03
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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

24 OCT 2020 10:28:28

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 11:20:03

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 22:14:05
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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	21 NOV 2020 08:13:45
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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

26 NOV 2020 19:01:00

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 16:42:37
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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

09 DEC 2020 14:04:31

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 09:22:52
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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

23 DEC 2020 08:28:29

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 08:13:27
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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

06 JAN 2021 10:32:06

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

<b>TIMEPOINT</b>	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 <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	15 JAN 2021 17:15:59
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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

20 JAN 2021 06:14:36

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 14:33:41

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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

03 FEB 2021 16:37:09

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 18:30:01
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 08:06:40
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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	24 FEB 2021 23:28:11
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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

05 MAR 2021 06:18:51

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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

10 MAR 2021 15:57:45

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

<b>TIMEPOINT</b>	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 14:00:08
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 06:29:13

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

<b>TIMEPOINT</b>	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 MAR 2021 05:28:18
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

<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	07 APR 2021 08:38:08
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 08:10:01

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 10:05:38

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 07:28:36

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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26 SEP 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 NOV 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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 <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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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05 DEC 2021 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	29 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUL 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Open Date & Time](#)

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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**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 ☐

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59



US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

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

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[Patient Cloud Close Date & Time](#)

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23 OCT 2022 23:59

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US3552053

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:08:15

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
Yes	No	05 MAR 2021 06:19:15

US3552053

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552053

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552053

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3552053

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552053

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:36:43

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:19:04

Generated On: 10 Jun 2021 08:08:15

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) \_\_\_\_\_

US3552053

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 16:19:04

Generated On: 10 Jun 2021 08:08:15

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.*

US3552053

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 MAR 2021

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

01 MAR 2021 11:40

US3552053

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3552053

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3552053

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552053

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

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*

**US3552053**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:08:15**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552053

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:08:15

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"/>

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3552053

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

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

Visit date (dd MMM yyyy)	11 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3552053

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:22:23

Generated On: 10 Jun 2021 08:08:15

Date of updated informed consent (dd MMM yyyy) 11 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) 11 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 \_\_\_\_\_



US3552053

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	09:55 (24 HR)
Collection date and time (derived)	11 JAN 2021 09:55

US3552053

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	10:00
Collection Date and Time (derived)	11 JAN 2021 10:00

US3552053

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

AEID	
Adverse event	TOOTH ACHE
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)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3552053

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

AEID	USA-US089-2020-MRNA-1273-P30 1000003
Adverse event	INTRACTABLE VOMITING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	15 SEP 2020
Start time (00:00-23:59)	12:00 (24 HR)
AE start date and time (derived)	15 SEP 2020 12:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	17 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	18 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

US3552053

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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SUBJECT CONTACTED SITE ON 9/16 TO REPORT MODERATE HEADACHE AND MILD NAUSEA WHICH STARTED ON 9/15; STATED HEADACHE HAD IMPROVED (MILD) BUT NAUSEA WAS SEVERE, ONGOING AND WORSENING. STATED SHE HAD NOT BEEN ABLE TO DRINK MUCH AND WASN'T ABLE TO KEEP FOOD DOWN. PER SUBJECT, ON 9/15, SHE DRANK "TWENTY TWO OUNCES" OF FLUID, NO FOOD, AND HAD "ONLY A FEW SIPS OF FLUIDS" ON 9/16 AT TIME OF CALL. SITE RECOMMENDED SHE VISIT URGENT CARE, WHICH SHE DID THE EVENING OF 9/16, RECEIVED FLUIDS AND A DOSE OF ZOFRAN. SITE CALLED TO FOLLOW UP THE MORNING OF 9/17, SUBJECT REPORTED FEELING MUCH BETTER AND THAT BOTH HEADACHE AND NAUSEA HAD IMPROVED TO MILD, AND THAT SHE HAD BEEN PROVIDED A PRESCRIPTION FOR ZOFRAN THAT SHE HAD NOT YET FILLED. SITE RECEIVED A CALL THE EVENING OF 9/17 FROM SUBJECT'S HUSBAND STATING THE SUBJECT'S SYMPTOMS



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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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HAD WORSENER AGAIN,  
SUBJECT WAS UNABLE TO  
KEEP FLUIDS DOWN AND THAT  
THEY WANTED TO GO TO THE  
EMERGENCY ROOM; THEY HAD  
FILLED THE ZOFRAN AND  
TAKEN A DOSE "A FEW  
MINUTES" BEFORE THE CALL  
WITHOUT IMPROVEMENT. SITE  
ADVISED THEM TO GO IF THEY  
FELT THEY NEEDED TO;  
SUBJECT'S HUSBAND  
MENTIONED DURING THE  
PHONE CALL THAT SUBJECT  
HAS A HISTORY OF  
HEADACHES WITH SEVERE  
NAUSEA THAT HAS LED TO  
HOSPITAL ADMISSIONS IN THE  
PAST. THE INFORMATION  
REGARDING HER HEADACHES  
HAD NOT BEEN PROVIDED TO  
SITE AT SCREENING PRIOR TO  
ENROLLMENT. SUBJECT WAS  
ADMITTED OVERNIGHT ON  
9/17, SUBJECT WAS  
DISCHARGED ON 18SEP2020.

---

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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US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 SEP 2020
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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

AEID	USA-US089-2020-MRNA-1273-P30 1000003
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	15 SEP 2020
Start time (00:00-23:59)	12:00 (24 HR)
AE start date and time (derived)	15 SEP 2020 12:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	17 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	18 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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SUBJECT CONTACTED SITE ON 9/16 TO REPORT MODERATE HEADACHE AND MILD NAUSEA WHICH STARTED ON 9/15; STATED HEADACHE HAD IMPROVED (MILD) BUT NAUSEA WAS SEVERE, ONGOING AND WORSENING. STATED SHE HAD NOT BEEN ABLE TO DRINK MUCH AND WASN'T ABLE TO KEEP FOOD DOWN. PER SUBJECT, ON 9/15, SHE DRANK "TWENTY TWO OUNCES" OF FLUID, NO FOOD, AND HAD "ONLY A FEW SIPS OF FLUIDS" ON 9/16 AT TIME OF CALL. SITE RECOMMENDED SHE VISIT URGENT CARE, WHICH SHE DID THE EVENING OF 9/16, RECEIVED FLUIDS AND A DOSE OF ZOFRAN. SITE CALLED TO FOLLOW UP THE MORNING OF 9/17, SUBJECT REPORTED FEELING MUCH BETTER AND THAT BOTH HEADACHE AND NAUSEA HAD IMPROVED TO MILD, AND THAT SHE HAD BEEN PROVIDED A PRESCRIPTION FOR ZOFRAN THAT SHE HAD NOT YET FILLED. SITE RECEIVED A CALL THE EVENING OF 9/17 FROM SUBJECT'S HUSBAND STATING THE SUBJECT'S SYMPTOMS

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

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HAD WORSENER AGAIN,  
SUBJECT WAS UNABLE TO  
KEEP FLUIDS DOWN AND THAT  
THEY WANTED TO GO TO THE  
EMERGENCY ROOM; THEY HAD  
FILLED THE ZOFRAN AND  
TAKEN A DOSE "A FEW  
MINUTES" BEFORE THE CALL  
WITHOUT IMPROVEMENT. SITE  
ADVISED THEM TO GO IF THEY  
FELT THEY NEEDED TO;  
SUBJECT'S HUSBAND  
MENTIONED DURING THE  
PHONE CALL THAT SUBJECT  
HAS A HISTORY OF  
HEADACHES WITH SEVERE  
NAUSEA THAT HAS LED TO  
HOSPITAL ADMISSIONS IN THE  
PAST. THE INFORMATION  
REGARDING HER HEADACHES  
HAD NOT BEEN PROVIDED TO  
SITE AT SCREENING PRIOR TO  
ENROLLMENT. SUBJECT WAS  
ADMITTED OVERNIGHT ON  
9/17, SUBJECT WAS  
DISCHARGED ON 18SEP2020.

---

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 (5)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

AEID

Adverse event

WORSENING PAROXYSMAL  
SUPRAVENTRICULAR  
TACHYCARDIA

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)

10 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 DEC 2020

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 ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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 (7)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

AEID	
Adverse event	MITRAL VALVE REGURGITATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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 (8)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

AEID

Adverse event

MIGRAINES/HEADACHE  
EXACERBATION

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)

19 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 DEC 2020

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 ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Mar 2021 16:50:55

Generated On: 10 Jun 2021 08:08:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

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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.

---

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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) _____		
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 (2)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 25

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

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

Name of Medication PRED FORTE 1%

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC RIGHT EYE UVEITIS

Dose per administration 1

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

If dose unit is Other, specify DROP

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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US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1989	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

Name of Medication KEFLEX

Prophylaxis Yes ☐  
No ☒

Indication TOOTHACHE

Dose per administration 500

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

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA, INTRACTABLE  
VOMITING

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA, INTRACTABLE  
VOMITING

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

	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)	18 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

Name of Medication IV FLUIDS

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA, INTRACTABLE  
VOMITING

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☒  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 17:58:25

Generated On: 10 Jun 2021 08:08:15

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552053

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 17:36:42

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---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3552053

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:08:15

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

US3552053

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:08:15

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 ☐

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	18/SEP/2020 13:48
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

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	22/SEP/2020 09:05
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

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	28/SEP/2020 07:59
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

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	29/SEP/2020 14:50
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.	True

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	06/OCT/2020 13:20
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

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	12/OCT/2020 12:35
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

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	12/OCT/2020 17:32
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

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	14/OCT/2020 13:04
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



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:07
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

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Data signed: (b) (4) 21 Feb 2021 17:36:42

Generated On: 10 Jun 2021 08:08:15

SAEID	USA-US089-2020-MRNA-1273-P301000003
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	SHARON
Investigator's Last Name	FREY
Site Address: Street	1100 S. GRAND BLVD
Site Address: City	ST. LOUIS
Site Address: State	MO
Site Address: Postal Code	63104
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	21/OCT/2020 16:40
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

US3552053 (Prod: Saint Louis University)

**US3552053**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:08:15**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'US3552053'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:04:46

US3552053

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:26

US3552053

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:04:46

US3552053

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:26

US3552053

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'SCRN'	System	18 Aug 2020 15:26:26



US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:04:47

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '65'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

**US3552053**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:08:15**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'YEARS'	System	18 Aug 2020 15:26:57

**US3552053**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:08:15**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '65'	System	17 Aug 2020 18:05:26

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Female (F)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57



US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

US3552053

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:15

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

**US3552053**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:08:15**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:26:57

US3552053

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:15

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 Aug 2020'	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:05:26



**US3552053**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:08:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Aug 2020'	System	17 Aug 2020 18:05:26

US3552053

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2020'	System	17 Aug 2020 18:05:26

US3552053

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:15

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Amendment 2 (2)'	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:05:26

US3552053

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:05:26

US3552053

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:15

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:05:26

US3552053

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:05:26

US3552053

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:05:26

US3552053

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:04:46



US3552053

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'l'	System	17 Aug 2020 18:05:34

US3552053

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:05:34

US3552053

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:08:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:28:25

US3552053

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Per DM CLR: Please update the MH procedure to confirm if the SYNOVIAL CYST REMOVAL was benign or cancerous. Ensure associated condition is updated so there is an appropriate match. Review and update as appropriate.' (Site from DM).	(b) (4) (u) (4), (b) (6)	02 Oct 2020 06:30:10
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:38:15
Query 'Per DM CLR: Please update the MH procedure to confirm if the SYNOVIAL CYST REMOVAL was benign or cancerous. Ensure associated condition is updated so there is an appropriate match. Review and update as appropriate.' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	29 Sep 2020 17:04:51
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	29 Sep 2020 17:04:43
User opened query 'Per DM CLR: Please update the MH procedure to confirm if the SYNOVIAL CYST REMOVAL was benign or cancerous. Ensure associated condition is updated so there is an appropriate match. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:49:42
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:47:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Synovial cyst removal, LLT: Synovial cyst removal - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 15:30:08

US3552053

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Aug 2020 15:30:08
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	18 Aug 2020 15:29:25
User entered 'synovial cyst removal'	Stanley Doublin (b) (4)	18 Aug 2020 15:29:18
	(b) (4)	

US3552053

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Oct 2007'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:18

US3552053

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:18

US3552053

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:18



US3552053

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Oct 2007'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:18

US3552053

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:18

**US3552053**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Oct 2007'	System	18 Aug 2020 15:29:18

**US3552053**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	18 Aug 2020 15:29:18

**US3552053**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Oct 2007'	System	18 Aug 2020 15:29:18

**US3552053**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	18 Aug 2020 15:29:18

US3552053

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (u) (*), (b) (6)	01 Oct 2020 12:42:49
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	29 Sep 2020 17:06:05
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:50:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Spinal fusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:31:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:31:07
Data point term sent to Coder	System	18 Aug 2020 15:30:27
User entered 'spinal fusion'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:46

US3552053

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Oct 2007'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:46



US3552053

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:46

US3552053

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:46

US3552053

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Oct 2007'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:46

US3552053

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:29:46

**US3552053**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Oct 2007'	System	18 Aug 2020 15:29:46

**US3552053**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	18 Aug 2020 15:29:46

**US3552053**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Oct 2007'	System	18 Aug 2020 15:29:46

**US3552053**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	18 Aug 2020 15:29:46



US3552053

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 15:31:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 15:31:06
Data point term sent to Coder	System	18 Aug 2020 15:30:27
User entered 'insomnia'	Stanley Dublin (b) (4)	18 Aug 2020 15:30:17

US3552053

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Jan 2007'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:30:17

US3552053

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:15

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:30:17

US3552053

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:30:17

US3552053

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:30:17

US3552053

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:30:17

**US3552053**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2007'	System	18 Aug 2020 15:30:17

**US3552053**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	18 Aug 2020 15:30:17



**US3552053**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:30:17

US3552053

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:30:17

US3552053

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User closed query 'Per DM CLR: Please specify the laterality of CHRONIC UVEITIS (e.g. Left, Right or Bilateral Eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:43:04
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Iris and uveal tract infections, irritations and inflammations, PT: Uveitis, LLT: Uveitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:01:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:01:40
Data point term sent to Coder	System	29 Sep 2020 17:06:59
Query 'Per DM CLR: Please specify the laterality of CHRONIC UVEITIS (e.g. Left, Right or Bilateral Eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	29 Sep 2020 17:06:51
Coding entries removed.	Joan Siegner (b) (4)	29 Sep 2020 17:06:46
User entered 'CHRONIC right UVEITIS' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 17:06:46
User opened query 'Per DM CLR: Please specify the laterality of CHRONIC UVEITIS (e.g. Left, Right or Bilateral Eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:07:55
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Iris and uveal tract infections, irritations and inflammations, PT: Uveitis, LLT: Uveitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 16:19:12

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:15

[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)	18 Aug 2020 16:19:12
User entered 'chronic uveitis'	System	18 Aug 2020 15:33:32
	Stanley Dublin (b) (4)	18 Aug 2020 15:33:09
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un UNK 1989'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:09

US3552053

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:09

US3552053

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:09

US3552053

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:09



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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:09

**US3552053**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 1989'	System	18 Aug 2020 15:33:09

**US3552053**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '1989'	System	18 Aug 2020 15:33:09

US3552053

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:33:09

**US3552053**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:33:09

US3552053

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Paralysis and paresis (excl cranial nerve), PT: Hemiparesis, LLT: Weakness left or right side - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 10:04:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 10:04:20
Data point term sent to Coder	System	18 Aug 2020 15:34:33
User entered 'left sided weakness'	Stanley Doublin (b) (4)	18 Aug 2020 15:33:35

US3552053

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Jan 2007'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:35

US3552053

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:35



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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:35

US3552053

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:35

US3552053

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:35

**US3552053**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2007'	System	18 Aug 2020 15:33:35

**US3552053**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	18 Aug 2020 15:33:35

**US3552053**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:33:35

**US3552053**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:33:35

US3552053

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Hypoaesthesia, LLT: Numbness in leg - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 11:48:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 11:48:36
Data point term sent to Coder	System	18 Aug 2020 15:34:33
User entered 'left calf numbness'	Stanley Dublin (b) (4)	18 Aug 2020 15:33:56



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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Oct 2007'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3552053

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3552053

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3552053

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:56

US3552053

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:33:56

**US3552053**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Oct 2007'	System	18 Aug 2020 15:33:56

**US3552053**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	18 Aug 2020 15:33:56

**US3552053**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:33:56



US3552053

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:33:56

US3552053

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:35:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:35:08
Data point term sent to Coder	System	18 Aug 2020 15:34:34
User entered 'kidney stones'	Stanley Dublin (b) (4)	18 Aug 2020 15:34:16

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Oct 2007'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:34:16

US3552053

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:34:16

US3552053

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
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	18 Aug 2020 15:34:29
User entered 'Yes (Y)' reason for change: Data Entry Error	System	18 Aug 2020 15:34:29
User opened query 'Data is required. Please complete.' (Site from System).	Stanley Dublin (b) (4)	18 Aug 2020 15:34:16
User entered empty.	System	18 Aug 2020 15:34:16
	Stanley Dublin (b) (4)	18 Aug 2020 15:34:16
	(b) (4)	

US3552053

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:34:16

US3552053

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:34:16

**US3552053**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Oct 2007'	System	18 Aug 2020 15:34:16



**US3552053**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	18 Aug 2020 15:34:16

**US3552053**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:34:16

US3552053

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	18 Aug 2020 15:34:16

US3552053

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:36:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:36:08
Data point term sent to Coder	System	18 Aug 2020 15:35:35
User entered 'left meniscus tear'	Stanley Dublin (b) (4)	18 Aug 2020 15:35:03

US3552053

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Jan 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:35:03

US3552053

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:35:03

US3552053

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:35:03

US3552053

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un May 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:35:03



US3552053

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:35:03

**US3552053**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2020'	System	18 Aug 2020 15:35:03

**US3552053**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2020'	System	18 Aug 2020 15:35:03

**US3552053**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'May 2020'	System	18 Aug 2020 15:35:03

**US3552053**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2020'	System	18 Aug 2020 15:35:03

US3552053

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 16:21:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 16:21:12
Data point term sent to Coder	System	18 Aug 2020 15:36:39
User entered 'left meniscus arthroscopic repair'	Stanley Doublin (b) (4)	18 Aug 2020 15:36:08

US3552053

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un May 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:08

US3552053

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:08



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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:08

US3552053

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un May 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:08

US3552053

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:08

**US3552053**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'May 2020'	System	18 Aug 2020 15:36:08

**US3552053**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2020'	System	18 Aug 2020 15:36:08

**US3552053**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'May 2020'	System	18 Aug 2020 15:36:08

**US3552053**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2020'	System	18 Aug 2020 15:36:08

US3552053

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:38:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:38:23
Data point term sent to Coder	System	18 Aug 2020 15:37:43
User entered 'hysterectomy'	Stanley Doublin (b) (4)	18 Aug 2020 15:36:45



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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Aug 1996'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:45

US3552053

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:45

US3552053

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:45

US3552053

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Aug 1996'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:45

US3552053

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:36:45

**US3552053**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Aug 1996'	System	18 Aug 2020 15:36:45

**US3552053**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '1996'	System	18 Aug 2020 15:36:45

**US3552053**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Aug 1996'	System	18 Aug 2020 15:36:45



**US3552053**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '1996'	System	18 Aug 2020 15:36:45

US3552053

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:38:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:38:23
Data point term sent to Coder	System	18 Aug 2020 15:37:43
User entered 'endometriosis'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:37:13

US3552053

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un UNK 1985'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:37:13

US3552053

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:37:13

US3552053

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:37:13

US3552053

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Aug 1996'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:37:13

US3552053

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:37:13

**US3552053**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 1985'	System	18 Aug 2020 15:37:13



**US3552053**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '1985'	System	18 Aug 2020 15:37:13

**US3552053**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Aug 1996'	System	18 Aug 2020 15:37:13

**US3552053**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '1996'	System	18 Aug 2020 15:37:13

US3552053

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunionectomy - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 16:18:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 16:18:17
Data point term sent to Coder	System	18 Aug 2020 15:41:52
User entered 'bunionectomy left first metatarsal and 5th metatarsal'	Stanley Doublin (b) (4)	18 Aug 2020 15:41:29

US3552053

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:29

US3552053

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:29

US3552053

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:29

US3552053

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:29



US3552053

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:29

US3552053

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2018'	System	18 Aug 2020 15:41:29

US3552053

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2018'	System	18 Aug 2020 15:41:29

US3552053

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2018'	System	18 Aug 2020 15:41:29

**US3552053**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2018'	System	18 Aug 2020 15:41:29

US3552053

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunionectomy - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 16:18:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 16:18:17
Data point term sent to Coder	System	18 Aug 2020 15:41:55
User entered 'bunionectomy right first metatarsal and 5th metatarsal'	Stanley Doublin (b) (4)	18 Aug 2020 15:41:53

US3552053

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:53

US3552053

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:53



US3552053

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:53

US3552053

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:53

US3552053

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:41:53

**US3552053**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2018'	System	18 Aug 2020 15:41:53

US3552053

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2018'	System	18 Aug 2020 15:41:53

**US3552053**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2018'	System	18 Aug 2020 15:41:53

**US3552053**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2018'	System	18 Aug 2020 15:41:53

US3552053

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Per DM CLR: Please specify the location and/or type of BUNIONS (e.g. Left 1st and 5th Metatarsal, Right 1st and 5th Metatarsal etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4)	02 Oct 2020 06:30:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Extremity deformities, PT: Foot deformity, LLT: Bunion - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 12:50:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 12:50:48
Data point term sent to Coder	System	29 Sep 2020 17:03:53
Query 'Per DM CLR: Please specify the location and/or type of BUNIONS (e.g. Left 1st and 5th Metatarsal, Right 1st and 5th Metatarsal etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	29 Sep 2020 17:03:31
Coding entries removed.	Joan Siegner (b) (4)	29 Sep 2020 17:03:26
User entered 'BUNIONS: left first metatarsal and 5th metatarsal, right first metatarsal and 5th metatarsal' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 17:03:26
User opened query 'Per DM CLR: Please specify the location and/or type of BUNIONS (e.g. Left 1st and 5th Metatarsal, Right 1st and 5th Metatarsal etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:09:57



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Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Extremity deformities, PT: Foot deformity, LLT: Bunion - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:44:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:44:15
Data point term sent to Coder	System	18 Aug 2020 15:42:59
User entered 'bunions'	Stanley Doublin (b) (4)	18 Aug 2020 15:42:18

US3552053

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:42:18

US3552053

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:42:18

US3552053

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:42:18

US3552053

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:42:18

US3552053

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:42:18

**US3552053**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2018'	System	18 Aug 2020 15:42:18

**US3552053**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2018'	System	18 Aug 2020 15:42:18



**US3552053**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2018'	System	18 Aug 2020 15:42:18

**US3552053**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2018'	System	18 Aug 2020 15:42:18

US3552053

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve prolapse, LLT: Mitral valve prolapse - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 12:59:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 12:59:36
Data point term sent to Coder	System	22 Sep 2020 12:58:09
User entered 'mitral valve prolapse'	Joan Siegner (b) (4)	22 Sep 2020 12:57:32

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Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:57:32

US3552053

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'l'	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:57:32

**US3552053**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:08:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:57:32

US3552053

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:57:32

**US3552053**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:57:32



**US3552053**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	22 Sep 2020 12:57:32

**US3552053**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	22 Sep 2020 12:57:32

**US3552053**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	22 Sep 2020 12:57:32

US3552053

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	22 Sep 2020 12:57:32

US3552053

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 13:00:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 13:00:39
Data point term sent to Coder	System	22 Sep 2020 12:59:12
User entered 'irritable bowel disease'	Joan Siegner (b) (4)	22 Sep 2020 12:58:16

US3552053

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:58:16

**US3552053**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:08:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'l'	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:58:16

**US3552053**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:08:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:58:16



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Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:58:16

US3552053

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Joan Siegner (b) (4)	22 Sep 2020 12:58:16

US3552053

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	22 Sep 2020 12:58:16

**US3552053**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	22 Sep 2020 12:58:16

US3552053

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	22 Sep 2020 12:58:16

US3552053

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	22 Sep 2020 12:58:16

US3552053

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Gastrointestinal disorders, HLGt: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:11:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:11:36
User coded data point as SOC: Gastrointestinal disorders, HLGt: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:50:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:50:26
Data point term sent to Coder	System	09 Oct 2020 15:49:27
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) HEADACHES 2) NAUSEA' (Site from System).	System	09 Oct 2020 15:48:42
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) HEADACHES 2) NAUSEA' answered with 'updated' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 15:48:42
User entered 'NAUSEA' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 15:48:38
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) HEADACHES 2) NAUSEA' (Site from System).	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:42:09
Data point term sent to Coder	System	29 Sep 2020 17:01:49
User entered 'headaches with nausea'	Joan Siegner (b) (4) (b) (4)	29 Sep 2020 17:01:13

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Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:01:13



**US3552053**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:08:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'l'	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:01:13

**US3552053**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:08:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:01:13

US3552053

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:01:13

US3552053

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:01:13

**US3552053**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	29 Sep 2020 17:01:13

**US3552053**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	29 Sep 2020 17:01:13

**US3552053**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	29 Sep 2020 17:01:13

**US3552053**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	29 Sep 2020 17:01:13



US3552053

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Synovial disorders, PT: Synovial cyst, LLT: Synovial cyst - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 21:40:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 21:40:36
Data point term sent to Coder	System	29 Sep 2020 17:05:58
User entered 'benign synovial cyst'	Joan Siegner (b) (4)	29 Sep 2020 17:05:33

US3552053

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Oct 2007'	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:05:33

US3552053

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:05:33

**US3552053**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:08:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:05:33

US3552053

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Oct 2007'	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:05:33

**US3552053**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Joan Siegner (b) (4)	29 Sep 2020 17:05:33

**US3552053**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Oct 2007'	System	29 Sep 2020 17:05:33

**US3552053**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	29 Sep 2020 17:05:33



**US3552053**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Oct 2007'	System	29 Sep 2020 17:05:33

**US3552053**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	29 Sep 2020 17:05:33

US3552053

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 15:51:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 15:51:28
Data point term sent to Coder	System	09 Oct 2020 15:50:31
User entered 'Headaches'	Cassandra Zehenny (b) (4)	09 Oct 2020 15:49:37

US3552053

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'un Oct 2007'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 15:49:37

**US3552053**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:08:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 15:49:37

US3552053

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 15:49:37

US3552053

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 15:49:37

US3552053

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 15:49:37



US3552053

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Oct 2007'	System	09 Oct 2020 15:49:37

**US3552053**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2007'	System	09 Oct 2020 15:49:37

**US3552053**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	09 Oct 2020 15:49:37

**US3552053**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	09 Oct 2020 15:49:37

US3552053

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Paroxysmal supraventricular tachycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:17:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:17:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 16:50:55
Data point term sent to Coder	System	01 Mar 2021 19:38:27
Coding entries removed.	Heather Douds (b) (4) (b) (4)	01 Mar 2021 19:38:20
Signature has been broken.	Heather Douds (b) (4) (b) (4)	01 Mar 2021 19:38:20
User entered 'cardiac arrhythmia - paroxysmal supraventricular tachycardia' reason for change: New Information	Heather Douds (b) (4) (b) (4)	01 Mar 2021 19:38:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 07:23:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 07:23:58
Data point term sent to Coder	System	30 Nov 2020 19:24:57
User entered 'Pre-ventricular contractions'	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 19:24:07

US3552053

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 19:24:07

US3552053

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 19:24:07

**US3552053**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:08:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 19:24:07



US3552053

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 19:24:07

US3552053

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 19:24:07

**US3552053**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	30 Nov 2020 19:24:07

**US3552053**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	30 Nov 2020 19:24:07

US3552053

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	30 Nov 2020 19:24:07

**US3552053**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	30 Nov 2020 19:24:07

US3552053

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin dystrophies, PT: Skin wrinkling, LLT: Wrinkles - version MedDRA\23.0.	Coder Import (b) (4)	05 Mar 2021 15:32:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Mar 2021 15:32:53
Data point term sent to Coder	System	05 Mar 2021 15:32:23
User entered 'rhytids'	Stanley Dublin (b) (4)	05 Mar 2021 15:32:05

US3552053

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 15:32:05



US3552053

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 15:32:05

US3552053

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 15:32:05

US3552053

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 15:32:05

US3552053

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 15:32:05

**US3552053**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'Jan 2018'	System	05 Mar 2021 15:32:05

**US3552053**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:08:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '2018'	System	05 Mar 2021 15:32:05

**US3552053**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	05 Mar 2021 15:32:05

**US3552053**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:08:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered empty.	System	05 Mar 2021 15:32:05



US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '11:42'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:43:37

**US3552053**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:08:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered '17 Aug 2020 11:42'	System	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '67' in	(b) (4) Stanley Dublin (b) (4)	18 Aug 2020 15:43:37
DataPoint set to visible.	(b) (4) System	17 Aug 2020 18:05:34

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '170.6' lb	(b) (4) Stanley Dublin (b) (4)	18 Aug 2020 15:43:37
DataPoint set to visible.	(b) (4) System	17 Aug 2020 18:05:34

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
Amendment Manager: User entered '26.77561'	System	17 Sep 2020 00:00:26
User entered '26.8'	System	18 Aug 2020 15:43:37
DataPoint set to visible.	System	17 Aug 2020 18:05:34

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'kg/m2'	System	18 Aug 2020 15:43:37
DataPoint set to visible.	System	17 Aug 2020 18:05:34



US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'nd' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 11:21:31
User opened query 'Data is required. Please provide.' (Site from System).	Stanley Doublin (b) (4)	18 Aug 2020 15:43:43
User entered empty.	(b) (4)	
	System	18 Aug 2020 15:43:37
	Stanley Doublin (b) (4)	18 Aug 2020 15:43:37
	(b) (4)	

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'bpm'	System	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4)	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'breaths/min'	System	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:43:37



US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'mmHg'	System	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User entered 'mmHg'	System	18 Aug 2020 15:43:37

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40

US3552053

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40

US3552053

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:44:42

US3552053

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4)	25 Sep 2020 04:58:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(u) (4), (b) (6)	14 Sep 2020 19:09:50
User entered '17 Aug 2020'	Stanley Dublin (b) (4)	18 Aug 2020 15:44:42
	(b) (4)	

US3552053

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:46:37



US3552053

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:15

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:46:37

US3552053

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:15

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:46:37

US3552053

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:15

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:46:37

US3552053

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'un Aug 1996'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:46:37

US3552053

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:15

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:46:37

US3552053

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:46:37

US3552053

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:15

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:46:37

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09



US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

**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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

**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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

**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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

**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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09



US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

**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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

**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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'BABY SITTING GRANDCHILDREN TWICE A WEEK, WEEKLY DINNERS WITH CHILDREN, WEEKLY GROCERY STORE TRIPS' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	18 Aug 2020 19:24:39
User entered 'baby sitting grandchildren twice a weekly, weekly dinners with children, weekly grocery store trips'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

**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 21:25:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '0'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09



US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

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 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:09

US3552053

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:28

US3552053

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:28

US3552053

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:36:45
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:28

**US3552053**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:08:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'VISIT1'	System	18 Aug 2020 15:48:28



US3552053

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:05:19

US3552053

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:15

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:36:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:05:17
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:05:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 18:05:19
User entered '186595' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:05:19

US3552053

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:05:19

US3552053

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:15

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:41

US3552053

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:15

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:41

US3552053

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:15

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 15:48:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 15:48:51
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	18 Aug 2020 15:48:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 15:48:41
User entered empty.	System	18 Aug 2020 15:48:41
	Stanley Dublin (b) (4)	18 Aug 2020 15:48:41
	(b) (4)	

US3552053

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:15

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:41

US3552053

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:48:41



US3552053

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:15

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 17:03:38
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:41:50

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59



US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '11:42'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '17 Aug 2020 11:42'	System	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '97.6' F	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '52'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'bpm'	System	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '16'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59



US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'breaths/min'	System	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '132'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '86'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:49:59

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:50:39



US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:05:13
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'data is correct' (Site from System).	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:46
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	18 Aug 2020 15:50:39
User entered '14:06'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '17 Aug 2020 14:06'	System	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 04:19:30
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Heather Douds (b) (4) (b) (4)	22 Sep 2020 15:44:50
answered with 'NCS' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:00:26
User entered '96.5' F	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '48'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39



**US3552053**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'bpm'	System	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '16'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'breaths/min'	System	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '142'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '72'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	18 Aug 2020 15:50:39

US3552053

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 19:10:08



US3552053

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 19:10:08

US3552053

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:43:49

US3552053

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:43:49

US3552053

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:43:49

US3552053

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 18:43:49

US3552053

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 Aug 2020'	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:43:49

US3552053

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '13:36'	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:43:49

**US3552053**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:08:15**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '17 Aug 2020 13:36'	System	17 Aug 2020 18:43:49



US3552053

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (u) (4), (b) (6)	17 Aug 2020 18:43:49

US3552053

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'ONCE'	System	17 Aug 2020 18:43:49

US3552053

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 18:43:49

US3552053

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:51:28

US3552053

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:51:28

US3552053

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '12:50'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:51:28

**US3552053**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:08:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '17 Aug 2020 12:50'	System	18 Aug 2020 15:51:28

US3552053

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '17 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:51:44



US3552053

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:51:44

US3552053

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:51:44

US3552053

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '12:54'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:51:44

**US3552053**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '17 Aug 2020 12:54'	System	18 Aug 2020 15:51:44

US3552053

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:51:49

US3552053

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:51:49

US3552053

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:51:49

**US3552053**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered empty.	System	18 Aug 2020 15:51:49



US3552053

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 15:22:17

US3552053

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'I'	System	24 Aug 2020 15:22:17

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:07:10', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '58d87bc3-6c8f-46c0-a999-020d09696d1e' User entered 'Yes (Y)'	System	17 Aug 2020 19:08:07
	System	17 Aug 2020 19:08:07

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:07:28', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '58d87bc3-6c8f-46c0-a999-020d09696d1e' User entered '96.5'	System	17 Aug 2020 19:08:07
	System	17 Aug 2020 19:08:07

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:07:50', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '58d87bc3-6c8f-46c0-a999-020d09696d1e' User entered 'No (N)'	System	17 Aug 2020 19:08:07
	System	17 Aug 2020 19:08:07

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:08:03', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '58d87bc3-6c8f-46c0-a999-020d09696d1e' User entered '17 Aug 2020 14:08'	System	17 Aug 2020 19:08:07
	System	17 Aug 2020 19:08:07

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Aug 2020 13:56'	System	17 Aug 2020 18:43:49



US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Aug 2020 16:26'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:16:43', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '9201f119-b4a7-418d-8b93-b9b43f8c8fa0' User entered 'Yes (Y)'	System	17 Aug 2020 23:17:06
	System	17 Aug 2020 23:17:06

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:16:51', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '9201f119-b4a7-418d-8b93-b9b43f8c8fa0' User entered '96.3'	System	17 Aug 2020 23:17:06
	System	17 Aug 2020 23:17:06

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:16:55', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '9201f119-b4a7-418d-8b93-b9b43f8c8fa0'	System	17 Aug 2020 23:17:06
User entered 'No (N)'	System	17 Aug 2020 23:17:06

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:02', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '9201f119-b4a7-418d-8b93-b9b43f8c8fa0' User entered '17 Aug 2020 18:17'	System	17 Aug 2020 23:17:06
	System	17 Aug 2020 23:17:06

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Aug 2020 17:21'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 18:43:49



US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 2'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:46:24', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fe831008-e343-4af7-993e-5fb998e41fbb' User entered 'Yes (Y)'	System	18 Aug 2020 19:46:45
	System	18 Aug 2020 19:46:45

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:46:31', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fe831008-e343-4af7-993e-5fb998e41fbb' User entered '97.9'	System	18 Aug 2020 19:46:45
	System	18 Aug 2020 19:46:45

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:46:35', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fe831008-e343-4af7-993e-5fb998e41fbb'	System	18 Aug 2020 19:46:45
User entered 'No (N)'	System	18 Aug 2020 19:46:45

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:46:40', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fe831008-e343-4af7-993e-5fb998e41fbb' User entered '18 Aug 2020 14:46'	System	18 Aug 2020 19:46:45
	System	18 Aug 2020 19:46:45

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 3'	System	17 Aug 2020 18:43:49



US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:19', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd4208f0b-7aac-4bb4-a928-611a3394e94d' User entered 'Yes (Y)'	System	20 Aug 2020 01:03:32
	System	20 Aug 2020 01:03:32

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:25', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd4208f0b-7aac-4bb4-a928-611a3394e94d' User entered '97.8'	System	20 Aug 2020 01:03:32
	System	20 Aug 2020 01:03:32

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:28', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd4208f0b-7aac-4bb4-a928-611a3394e94d' User entered 'No (N)'	System	20 Aug 2020 01:03:32
	System	20 Aug 2020 01:03:32

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:31', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd4208f0b-7aac-4bb4-a928-611a3394e94d' User entered '19 Aug 2020 20:03'	System	20 Aug 2020 01:03:32
	System	20 Aug 2020 01:03:32

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 4'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:08', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ac2e0ad6-3774-466e-94b8-b3e87f689a2d' User entered 'Yes (Y)'	System	20 Aug 2020 23:14:23
	System	20 Aug 2020 23:14:23



US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:14', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ac2e0ad6-3774-466e-94b8-b3e87f689a2d' User entered '97.6'	System	20 Aug 2020 23:14:23
	System	20 Aug 2020 23:14:23

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:17', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ac2e0ad6-3774-466e-94b8-b3e87f689a2d'	System	20 Aug 2020 23:14:23
User entered 'No (N)'	System	20 Aug 2020 23:14:23

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:20', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ac2e0ad6-3774-466e-94b8-b3e87f689a2d' User entered '20 Aug 2020 18:14'	System	20 Aug 2020 23:14:23
	System	20 Aug 2020 23:14:23

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 5'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:06', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7ce9191e-7c46-43fa-ae05-1dae8dc3b303'	System	21 Aug 2020 23:46:21
User entered 'Yes (Y)'	System	21 Aug 2020 23:46:21

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:11', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7ce9191e-7c46-43fa-ae05-1dae8dc3b303' User entered '97.1'	System	21 Aug 2020 23:46:21
	System	21 Aug 2020 23:46:21



US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:14', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7ce9191e-7c46-43fa-ae05-1dae8dc3b303'	System	21 Aug 2020 23:46:21
User entered 'No (N)'	System	21 Aug 2020 23:46:21

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:17', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7ce9191e-7c46-43fa-ae05-1dae8dc3b303'	System	21 Aug 2020 23:46:21
User entered '21 Aug 2020 18:46'	System	21 Aug 2020 23:46:21

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 6'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:04:46', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '3c058495-f5f2-4e28-879e-8b427f83aeaa'	System	23 Aug 2020 02:05:01
User entered 'Yes (Y)'	System	23 Aug 2020 02:05:01

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:04:52', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '3c058495-f5f2-4e28-879e-8b427f83aeaa' User entered '97.3'	System	23 Aug 2020 02:05:01
	System	23 Aug 2020 02:05:01

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:04:55', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '3c058495-f5f2-4e28-879e-8b427f83aeaa'	System	23 Aug 2020 02:05:01
User entered 'No (N)'	System	23 Aug 2020 02:05:01



US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:04:59', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '3c058495-f5f2-4e28-879e-8b427f83aeaa'	System	23 Aug 2020 02:05:01
User entered '22 Aug 2020 21:04'	System	23 Aug 2020 02:05:01

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 7'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:09:41', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b3dff00d-65d6-4b13-b544-1407e57ca2f5'	System	24 Aug 2020 01:10:11
User entered 'Yes (Y)'	System	24 Aug 2020 01:10:11

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:09:49', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b3dff00d-65d6-4b13-b544-1407e57ca2f5' User entered '96.9'	System	24 Aug 2020 01:10:11
	System	24 Aug 2020 01:10:11

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:09:52', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b3dff00d-65d6-4b13-b544-1407e57ca2f5'	System	24 Aug 2020 01:10:11
User entered 'No (N)'	System	24 Aug 2020 01:10:11

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:09:57', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b3dff00d-65d6-4b13-b544-1407e57ca2f5'	System	24 Aug 2020 01:10:11
User entered '23 Aug 2020 20:09'	System	24 Aug 2020 01:10:11



US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:08:20', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fe70088-58e0-4967-bb0e-24f7491db6b4'	System	17 Aug 2020 19:08:55
User entered 'None (1)'	System	17 Aug 2020 19:08:55

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:08:28', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fe70088-58e0-4967-bb0e-24f7491db6b4'	System	17 Aug 2020 19:08:55
User entered 'No (N)'	System	17 Aug 2020 19:08:55

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:08:33', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fe70088-58e0-4967-bb0e-24f7491db6b4'	System	17 Aug 2020 19:08:55
User entered 'No (N)'	System	17 Aug 2020 19:08:55

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:08:44', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fe70088-58e0-4967-bb0e-24f7491db6b4'	System	17 Aug 2020 19:08:55
User entered 'None (1)'	System	17 Aug 2020 19:08:55

**US3552053**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:08:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:08:52', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fe70088-58e0-4967-bb0e-24f7491db6b4' User entered '17 Aug 2020 14:08'	System	17 Aug 2020 19:08:55
	System	17 Aug 2020 19:08:55



US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Aug 2020 13:56'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Aug 2020 16:26'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:15', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '46735b91-c6d2-4100-bd30-c5a1acdbec6b' User entered 'None (1)'	System	17 Aug 2020 23:17:39
	System	17 Aug 2020 23:17:39

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:18', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '46735b91-c6d2-4100-bd30-c5a1acdbec6b' User entered 'No (N)'	System	17 Aug 2020 23:17:39
	System	17 Aug 2020 23:17:39

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:21', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '46735b91-c6d2-4100-bd30-c5a1acdbec6b' User entered 'No (N)'	System	17 Aug 2020 23:17:39
	System	17 Aug 2020 23:17:39

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:33', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '46735b91-c6d2-4100-bd30-c5a1acdbec6b' User entered 'None (1)'	System	17 Aug 2020 23:17:39
	System	17 Aug 2020 23:17:39

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:37', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '46735b91-c6d2-4100-bd30-c5a1acdbec6b' User entered '17 Aug 2020 18:17'	System	17 Aug 2020 23:17:39
	System	17 Aug 2020 23:17:39



US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Aug 2020 17:21'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 2'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:46:48', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c15a1349-bc02-4027-b14d-4e3688af452b'	System	18 Aug 2020 19:48:26
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 19:48:26

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:46:51', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c15a1349-bc02-4027-b14d-4e3688af452b' User entered 'No (N)'	System	18 Aug 2020 19:48:26
	System	18 Aug 2020 19:48:26

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:46:55', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c15a1349-bc02-4027-b14d-4e3688af452b' User entered 'Yes (Y)'	System	18 Aug 2020 19:48:26
	System	18 Aug 2020 19:48:26

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:47:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c15a1349-bc02-4027-b14d-4e3688af452b' User entered '4'	System	18 Aug 2020 19:48:26
	System	18 Aug 2020 19:48:26

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:06', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c15a1349-bc02-4027-b14d-4e3688af452b' User entered 'None (1)'	System	18 Aug 2020 19:48:26
	System	18 Aug 2020 19:48:26



US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:23', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c15a1349-bc02-4027-b14d-4e3688af452b' User entered '18 Aug 2020 14:48'	System	18 Aug 2020 19:48:26
	System	18 Aug 2020 19:48:26

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 3'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:35', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55d0d76e-88ba-4d06-8a64-6f9ebd525e88'	System	20 Aug 2020 01:03:50
User entered 'None (1)'	System	20 Aug 2020 01:03:50

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:38', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55d0d76e-88ba-4d06-8a64-6f9ebd525e88'	System	20 Aug 2020 01:03:50
User entered 'No (N)'	System	20 Aug 2020 01:03:50

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:41', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55d0d76e-88ba-4d06-8a64-6f9ebd525e88'	System	20 Aug 2020 01:03:50
User entered 'No (N)'	System	20 Aug 2020 01:03:50

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:45', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55d0d76e-88ba-4d06-8a64-6f9ebd525e88'	System	20 Aug 2020 01:03:50
User entered 'None (1)'	System	20 Aug 2020 01:03:50



US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:48', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55d0d76e-88ba-4d06-8a64-6f9ebd525e88' User entered '19 Aug 2020 20:03'	System	20 Aug 2020 01:03:50
	System	20 Aug 2020 01:03:50

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 4'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:25', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b5dbd30e-560b-4dae-9e1c-2c1040376894' User entered 'None (1)'	System	20 Aug 2020 23:14:42
	System	20 Aug 2020 23:14:42

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:28', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b5dbd30e-560b-4dae-9e1c-2c1040376894'	System	20 Aug 2020 23:14:42
User entered 'No (N)'	System	20 Aug 2020 23:14:42

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:31', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b5dbd30e-560b-4dae-9e1c-2c1040376894'	System	20 Aug 2020 23:14:42
User entered 'No (N)'	System	20 Aug 2020 23:14:42

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:34', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b5dbd30e-560b-4dae-9e1c-2c1040376894' User entered 'None (1)'	System	20 Aug 2020 23:14:42
	System	20 Aug 2020 23:14:42



US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:37', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b5dbd30e-560b-4dae-9e1c-2c1040376894' User entered '20 Aug 2020 18:14'	System	20 Aug 2020 23:14:42
	System	20 Aug 2020 23:14:42

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 5'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:21', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0704ca52-744e-4674-9cd6-a93906c5a7e1' User entered 'None (1)'	System	21 Aug 2020 23:46:35
	System	21 Aug 2020 23:46:35

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:24', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0704ca52-744e-4674-9cd6-a93906c5a7e1'	System	21 Aug 2020 23:46:35
User entered 'No (N)'	System	21 Aug 2020 23:46:35

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:27', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0704ca52-744e-4674-9cd6-a93906c5a7e1'	System	21 Aug 2020 23:46:35
User entered 'No (N)'	System	21 Aug 2020 23:46:35

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:30', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0704ca52-744e-4674-9cd6-a93906c5a7e1'	System	21 Aug 2020 23:46:35
User entered 'None (1)'	System	21 Aug 2020 23:46:35



US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:33', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0704ca52-744e-4674-9cd6-a93906c5a7e1' User entered '21 Aug 2020 18:46'	System	21 Aug 2020 23:46:35
	System	21 Aug 2020 23:46:35

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 6'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:04', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '68e18de7-6446-4b03-9dff-4e92258aa316' User entered 'None (1)'	System	23 Aug 2020 02:05:21
	System	23 Aug 2020 02:05:21

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:08', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '68e18de7-6446-4b03-9dff-4e92258aa316' User entered 'No (N)'	System	23 Aug 2020 02:05:21
	System	23 Aug 2020 02:05:21

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:11', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '68e18de7-6446-4b03-9dff-4e92258aa316' User entered 'No (N)'	System	23 Aug 2020 02:05:21
	System	23 Aug 2020 02:05:21

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:14', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '68e18de7-6446-4b03-9dff-4e92258aa316'	System	23 Aug 2020 02:05:21
User entered 'None (1)'	System	23 Aug 2020 02:05:21



**US3552053**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:08:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:17', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '68e18de7-6446-4b03-9dff-4e92258aa316' User entered '22 Aug 2020 21:05'	System	23 Aug 2020 02:05:21
	System	23 Aug 2020 02:05:21

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 7'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:01', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ac3774ee-7664-48b0-adb0-8cb3f12cf63c'	System	24 Aug 2020 01:10:20
User entered 'None (1)'	System	24 Aug 2020 01:10:20

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:03', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ac3774ee-7664-48b0-adb0-8cb3f12cf63c'	System	24 Aug 2020 01:10:20
User entered 'No (N)'	System	24 Aug 2020 01:10:20

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:05', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ac3774ee-7664-48b0-adb0-8cb3f12cf63c'	System	24 Aug 2020 01:10:20
User entered 'No (N)'	System	24 Aug 2020 01:10:20

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:08', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ac3774ee-7664-48b0-adb0-8cb3f12cf63c'	System	24 Aug 2020 01:10:20
User entered 'None (1)'	System	24 Aug 2020 01:10:20



**US3552053**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:08:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:10', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ac3774ee-7664-48b0-adb0-8cb3f12cf63c' User entered '23 Aug 2020 20:10'	System	24 Aug 2020 01:10:20
	System	24 Aug 2020 01:10:20

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 18:43:49

**US3552053**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:08:15**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:09:06', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55944096-999c-46d9-aa37-a9b6171a8477' User entered 'None (0)'	System	17 Aug 2020 19:09:39
	System	17 Aug 2020 19:09:39

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:09:11', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55944096-999c-46d9-aa37-a9b6171a8477' User entered 'None (0)'	System	17 Aug 2020 19:09:39
	System	17 Aug 2020 19:09:39

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:09:15', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55944096-999c-46d9-aa37-a9b6171a8477' User entered 'None (0)'	System	17 Aug 2020 19:09:39
	System	17 Aug 2020 19:09:39

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:09:19', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55944096-999c-46d9-aa37-a9b6171a8477'	System	17 Aug 2020 19:09:39
User entered 'No interference with activity (1)'	System	17 Aug 2020 19:09:39



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:09:22', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55944096-999c-46d9-aa37-a9b6171a8477' User entered 'None (0)'	System	17 Aug 2020 19:09:39
	System	17 Aug 2020 19:09:39

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:09:25', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55944096-999c-46d9-aa37-a9b6171a8477' User entered 'None (0)'	System	17 Aug 2020 19:09:39
	System	17 Aug 2020 19:09:39

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:09:29', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55944096-999c-46d9-aa37-a9b6171a8477'	System	17 Aug 2020 19:09:39
User entered 'No (N)'	System	17 Aug 2020 19:09:39

**US3552053**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:08:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T14:09:34', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '55944096-999c-46d9-aa37-a9b6171a8477' User entered '17 Aug 2020 14:09'	System	17 Aug 2020 19:09:39
	System	17 Aug 2020 19:09:39

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Aug 2020 13:56'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Aug 2020 16:26'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:42', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '134f5a70-c875-48a6-aab9-47fcb8500cdb' User entered 'None (0)'	System	17 Aug 2020 23:18:17
	System	17 Aug 2020 23:18:17



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:46', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '134f5a70-c875-48a6-aab9-47fcb8500cdb' User entered 'No interference with activity (1)'	System	17 Aug 2020 23:18:17
	System	17 Aug 2020 23:18:17

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:53', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '134f5a70-c875-48a6-aab9-47fcb8500cdb' User entered 'None (0)'	System	17 Aug 2020 23:18:17
	System	17 Aug 2020 23:18:17

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '134f5a70-c875-48a6-aab9-47fcb8500cdb' User entered 'No interference with activity (1)'	System	17 Aug 2020 23:18:17
	System	17 Aug 2020 23:18:17

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:17:59', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '134f5a70-c875-48a6-aab9-47fcb8500cdb' User entered 'None (0)'	System	17 Aug 2020 23:18:17
	System	17 Aug 2020 23:18:17

**US3552053**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:18:04', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '134f5a70-c875-48a6-aab9-47fcb8500cdb' User entered 'None (0)'	System	17 Aug 2020 23:18:17
	System	17 Aug 2020 23:18:17

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:18:09', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '134f5a70-c875-48a6-aab9-47fcb8500cdb' User entered 'No (N)'	System	17 Aug 2020 23:18:17
	System	17 Aug 2020 23:18:17

**US3552053**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:08:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-17T18:18:12', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '134f5a70-c875-48a6-aab9-47fcb8500cdb' User entered '17 Aug 2020 18:18'	System	17 Aug 2020 23:18:17
	System	17 Aug 2020 23:18:17

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Aug 2020 17:21'	System	17 Aug 2020 18:43:49



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 2'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:28', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '1d664c4a-04a4-4e3b-81f4-92237382af54' User entered 'None (0)'	System	18 Aug 2020 19:48:57
	System	18 Aug 2020 19:48:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:33', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '1d664c4a-04a4-4e3b-81f4-92237382af54'	System	18 Aug 2020 19:48:57
User entered 'No interference with activity (1)'	System	18 Aug 2020 19:48:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:37', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '1d664c4a-04a4-4e3b-81f4-92237382af54'	System	18 Aug 2020 19:48:57
User entered 'No interference with activity (1)'	System	18 Aug 2020 19:48:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:42', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '1d664c4a-04a4-4e3b-81f4-92237382af54'	System	18 Aug 2020 19:48:57
User entered 'No interference with activity (1)'	System	18 Aug 2020 19:48:57

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:46', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '1d664c4a-04a4-4e3b-81f4-92237382af54' User entered 'None (0)'	System	18 Aug 2020 19:48:57
	System	18 Aug 2020 19:48:57

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:49', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '1d664c4a-04a4-4e3b-81f4-92237382af54' User entered 'None (0)'	System	18 Aug 2020 19:48:57
	System	18 Aug 2020 19:48:57



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:52', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '1d664c4a-04a4-4e3b-81f4-92237382af54' User entered 'No (N)'	System	18 Aug 2020 19:48:57
	System	18 Aug 2020 19:48:57

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-18T14:48:55', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '1d664c4a-04a4-4e3b-81f4-92237382af54' User entered '18 Aug 2020 14:48'	System	18 Aug 2020 19:48:57
	System	18 Aug 2020 19:48:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 3'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:52', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'baa8ac24-1222-4c9c-85a4-875173401d45' User entered 'None (0)'	System	20 Aug 2020 01:04:15
	System	20 Aug 2020 01:04:15

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:54', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'baa8ac24-1222-4c9c-85a4-875173401d45' User entered 'None (0)'	System	20 Aug 2020 01:04:15
	System	20 Aug 2020 01:04:15

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:03:57', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'baa8ac24-1222-4c9c-85a4-875173401d45'	System	20 Aug 2020 01:04:15
User entered 'None (0)'	System	20 Aug 2020 01:04:15



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:04:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'baa8ac24-1222-4c9c-85a4-875173401d45' User entered 'None (0)'	System	20 Aug 2020 01:04:15
	System	20 Aug 2020 01:04:15

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:04:03', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'baa8ac24-1222-4c9c-85a4-875173401d45' User entered 'None (0)'	System	20 Aug 2020 01:04:15
	System	20 Aug 2020 01:04:15

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:04:05', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'baa8ac24-1222-4c9c-85a4-875173401d45'	System	20 Aug 2020 01:04:15
User entered 'None (0)'	System	20 Aug 2020 01:04:15

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:04:10', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'baa8ac24-1222-4c9c-85a4-875173401d45'	System	20 Aug 2020 01:04:15
User entered 'No (N)'	System	20 Aug 2020 01:04:15

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-19T20:04:13', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'baa8ac24-1222-4c9c-85a4-875173401d45' User entered '19 Aug 2020 20:04'	System	20 Aug 2020 01:04:15
	System	20 Aug 2020 01:04:15

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 4'	System	17 Aug 2020 18:43:49



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:41', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '85ee1428-2e6f-423b-860d-009fa4c97ffb' User entered 'None (0)'	System	20 Aug 2020 23:15:10
	System	20 Aug 2020 23:15:10

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:44', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '85ee1428-2e6f-423b-860d-009fa4c97ffb'	System	20 Aug 2020 23:15:10
User entered 'None (0)'	System	20 Aug 2020 23:15:10

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:46', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '85ee1428-2e6f-423b-860d-009fa4c97ffb'	System	20 Aug 2020 23:15:10
User entered 'None (0)'	System	20 Aug 2020 23:15:10

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:53', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '85ee1428-2e6f-423b-860d-009fa4c97ffb' User entered 'None (0)'	System	20 Aug 2020 23:15:10
	System	20 Aug 2020 23:15:10

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:14:58', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '85ee1428-2e6f-423b-860d-009fa4c97ffb' User entered 'None (0)'	System	20 Aug 2020 23:15:10
	System	20 Aug 2020 23:15:10

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:15:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '85ee1428-2e6f-423b-860d-009fa4c97ffb' User entered 'None (0)'	System	20 Aug 2020 23:15:10
	System	20 Aug 2020 23:15:10

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:15:03', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '85ee1428-2e6f-423b-860d-009fa4c97ffb'	System	20 Aug 2020 23:15:10
User entered 'No (N)'	System	20 Aug 2020 23:15:10

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-20T18:15:06', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '85ee1428-2e6f-423b-860d-009fa4c97ffb' User entered '20 Aug 2020 18:15'	System	20 Aug 2020 23:15:10
	System	20 Aug 2020 23:15:10



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 5'	System	17 Aug 2020 18:43:49

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:37', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fca4f2e7-1bd1-4db9-a674-6d823a1b68d7' User entered 'None (0)'	System	21 Aug 2020 23:46:57
	System	21 Aug 2020 23:46:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:40', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fca4f2e7-1bd1-4db9-a674-6d823a1b68d7' User entered 'None (0)'	System	21 Aug 2020 23:46:57
	System	21 Aug 2020 23:46:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:42', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fca4f2e7-1bd1-4db9-a674-6d823a1b68d7' User entered 'None (0)'	System	21 Aug 2020 23:46:57
	System	21 Aug 2020 23:46:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:45', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fca4f2e7-1bd1-4db9-a674-6d823a1b68d7' User entered 'None (0)'	System	21 Aug 2020 23:46:57
	System	21 Aug 2020 23:46:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:47', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fca4f2e7-1bd1-4db9-a674-6d823a1b68d7' User entered 'None (0)'	System	21 Aug 2020 23:46:57
	System	21 Aug 2020 23:46:57



**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:50', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fca4f2e7-1bd1-4db9-a674-6d823a1b68d7' User entered 'None (0)'	System	21 Aug 2020 23:46:57
	System	21 Aug 2020 23:46:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:53', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fca4f2e7-1bd1-4db9-a674-6d823a1b68d7' User entered 'No (N)'	System	21 Aug 2020 23:46:57
	System	21 Aug 2020 23:46:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-21T18:46:55', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'fca4f2e7-1bd1-4db9-a674-6d823a1b68d7' User entered '21 Aug 2020 18:46'	System	21 Aug 2020 23:46:57
	System	21 Aug 2020 23:46:57

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 6'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:25', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6f65cd7e-9d9f-403c-8d18-7d2164ed8a9b' User entered 'None (0)'	System	23 Aug 2020 02:05:52
	System	23 Aug 2020 02:05:52

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:28', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6f65cd7e-9d9f-403c-8d18-7d2164ed8a9b' User entered 'None (0)'	System	23 Aug 2020 02:05:52
	System	23 Aug 2020 02:05:52



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:31', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6f65cd7e-9d9f-403c-8d18-7d2164ed8a9b' User entered 'None (0)'	System	23 Aug 2020 02:05:52
	System	23 Aug 2020 02:05:52

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:34', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6f65cd7e-9d9f-403c-8d18-7d2164ed8a9b' User entered 'None (0)'	System	23 Aug 2020 02:05:52
	System	23 Aug 2020 02:05:52

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:37', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6f65cd7e-9d9f-403c-8d18-7d2164ed8a9b' User entered 'None (0)'	System	23 Aug 2020 02:05:52
	System	23 Aug 2020 02:05:52

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:39', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6f65cd7e-9d9f-403c-8d18-7d2164ed8a9b' User entered 'None (0)'	System	23 Aug 2020 02:05:52
	System	23 Aug 2020 02:05:52

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:46', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6f65cd7e-9d9f-403c-8d18-7d2164ed8a9b' User entered 'No (N)'	System	23 Aug 2020 02:05:52
	System	23 Aug 2020 02:05:52

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-22T21:05:49', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6f65cd7e-9d9f-403c-8d18-7d2164ed8a9b' User entered '22 Aug 2020 21:05'	System	23 Aug 2020 02:05:52
	System	23 Aug 2020 02:05:52

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 18:43:49



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 7'	System	17 Aug 2020 18:43:49

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:13', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fcacce8-b9eb-4f01-a79b-295fdd2a294e' User entered 'None (0)'	System	24 Aug 2020 01:10:37
	System	24 Aug 2020 01:10:37

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:17', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fcacce8-b9eb-4f01-a79b-295fdd2a294e' User entered 'None (0)'	System	24 Aug 2020 01:10:37
	System	24 Aug 2020 01:10:37

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:20', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fcacce8-b9eb-4f01-a79b-295fdd2a294e' User entered 'None (0)'	System	24 Aug 2020 01:10:37
	System	24 Aug 2020 01:10:37

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:22', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fcacce8-b9eb-4f01-a79b-295fdd2a294e' User entered 'None (0)'	System	24 Aug 2020 01:10:37
	System	24 Aug 2020 01:10:37

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:24', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fcacce8-b9eb-4f01-a79b-295fdd2a294e' User entered 'None (0)'	System	24 Aug 2020 01:10:37
	System	24 Aug 2020 01:10:37

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:26', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fcacce8-b9eb-4f01-a79b-295fdd2a294e' User entered 'None (0)'	System	24 Aug 2020 01:10:37
	System	24 Aug 2020 01:10:37

US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:28', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fcacce8-b9eb-4f01-a79b-295fdd2a294e' User entered 'No (N)'	System	24 Aug 2020 01:10:37
	System	24 Aug 2020 01:10:37



US3552053

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-08-23T20:10:31', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5fcacce8-b9eb-4f01-a79b-295fdd2a294e' User entered '23 Aug 2020 20:10'	System	24 Aug 2020 01:10:37
	System	24 Aug 2020 01:10:37

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 18:43:49

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 15:22:38

US3552053

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '24 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 15:22:38

US3552053

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 15:22:38

US3552053

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 15:22:38

US3552053

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 16:45:06



US3552053

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User entered 'l'	System	31 Aug 2020 16:45:06

US3552053

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 16:45:17

US3552053

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '31 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 16:45:17

US3552053

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 16:45:17

US3552053

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	31 Aug 2020 16:45:17

US3552053

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Sep 2020 13:11:21

US3552053

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User entered 'l'	System	08 Sep 2020 13:11:21

US3552053

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	08 Sep 2020 13:11:55



US3552053

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '07 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:27:09
User entered '7 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 13:11:55

US3552053

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	08 Sep 2020 13:11:55

US3552053

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	08 Sep 2020 13:11:55

US3552053

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Sep 2020 17:59:27

US3552053

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User entered 'l'	System	14 Sep 2020 17:59:27

US3552053

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:09:50

US3552053

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '14 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:09:50

US3552053

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered 'Home (Home)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:09:50



US3552053

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'VISIT2'	System	14 Sep 2020 19:09:50

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User accepted default value 'Pre-Dose (PREDOSE)'	Joan Siegner (b) (4)	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '14 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '12:02'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:05

**US3552053**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '14 Sep 2020 12:02'	System	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '98.3' F	Joan Siegner (b) (4)	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered 'Oral (Oral)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:05



US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered empty.	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '64'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'bpm'	System	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '15'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'breaths/min'	System	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '146'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '88'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:05



US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	14 Sep 2020 19:13:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User accepted default value 'Post-Dose (POSTDOSE)'	Joan Siegner (b) (4)	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '14 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '13:33'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '14 Sep 2020 13:33'	System	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '98.3' F	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered 'Oral (Oral)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:33



US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered empty.	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '55'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'bpm'	System	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '16'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'breaths/min'	System	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '120'	Joan Siegner (b) (4)	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '78'	Joan Siegner (b) (4)	14 Sep 2020 19:13:33



US3552053

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	14 Sep 2020 19:13:33

US3552053

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:50

US3552053

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '14 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:13:50

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:07:51

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:07:51

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:07:51

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 18:07:51

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:07:51



US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '13:03'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:07:51

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '14 Sep 2020 13:03'	System	14 Sep 2020 18:07:51

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:07:51

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'ONCE'	System	14 Sep 2020 18:07:51

US3552053

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 18:07:51

US3552053

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:14:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '14 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:14:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '12:29'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:14:05



US3552053

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '14 Sep 2020 12:29'	System	14 Sep 2020 19:14:05

US3552053

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '14 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:14:20

**US3552053**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Joan Siegner (b) (4)	14 Sep 2020 19:14:20

US3552053

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:14:20

US3552053

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '12:33'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:14:20

**US3552053**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '14 Sep 2020 12:33'	System	14 Sep 2020 19:14:20

US3552053

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Joan Siegner (b) (4)	14 Sep 2020 19:14:20

US3552053

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:14:20



US3552053

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 19:14:20

US3552053

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered empty.	System	14 Sep 2020 19:14:20

US3552053

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:02:29

US3552053

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'I'	System	21 Sep 2020 14:02:29

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:31:29', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd15497db-e706-4225-90a0-56c98edecd03' User entered 'Yes (Y)'	System	14 Sep 2020 18:32:19
	System	14 Sep 2020 18:32:19

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:31:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd15497db-e706-4225-90a0-56c98edecd03' User entered '98.3'	System	14 Sep 2020 18:32:19
	System	14 Sep 2020 18:32:19

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:31:39', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd15497db-e706-4225-90a0-56c98edecd03'	System	14 Sep 2020 18:32:19
User entered 'No (N)'	System	14 Sep 2020 18:32:19



US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:31:43', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd15497db-e706-4225-90a0-56c98edecd03'	System	14 Sep 2020 18:32:19
User entered '14 Sep 2020 13:31'	System	14 Sep 2020 18:32:19

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '14 Sep 2020 13:23'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '14 Sep 2020 15:53'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c1a9638a-292c-4b53-8a3f-62b15b985c3c' User entered 'Yes (Y)'	System	14 Sep 2020 23:51:13
	System	14 Sep 2020 23:51:13

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:06', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c1a9638a-292c-4b53-8a3f-62b15b985c3c' User entered '97.9'	System	14 Sep 2020 23:51:13
	System	14 Sep 2020 23:51:13

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:08', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c1a9638a-292c-4b53-8a3f-62b15b985c3c' User entered 'No (N)'	System	14 Sep 2020 23:51:13
	System	14 Sep 2020 23:51:13

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:11', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'c1a9638a-292c-4b53-8a3f-62b15b985c3c' User entered '14 Sep 2020 18:51'	System	14 Sep 2020 23:51:13
	System	14 Sep 2020 23:51:13



US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '14 Sep 2020 16:48'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 2'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:08:15', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b4c8fa2b-4c8c-4ba0-aec0-023f288c63e1' User entered 'Yes (Y)'	System	15 Sep 2020 17:08:39
	System	15 Sep 2020 17:08:39

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:08:25', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b4c8fa2b-4c8c-4ba0-aec0-023f288c63e1' User entered '101.0'	System	15 Sep 2020 17:08:39
	System	15 Sep 2020 17:08:39

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:08:30', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b4c8fa2b-4c8c-4ba0-aec0-023f288c63e1' User entered 'No (N)'	System	15 Sep 2020 17:08:39
	System	15 Sep 2020 17:08:39

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:08:35', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b4c8fa2b-4c8c-4ba0-aeec-023f288c63e1' User entered '15 Sep 2020 12:08'	System	15 Sep 2020 17:08:39
	System	15 Sep 2020 17:08:39

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 18:07:51



US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 3'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:03:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '94aa2b7e-2e61-4975-ac8e-233602bd8e5a' User entered 'Yes (Y)'	System	16 Sep 2020 18:03:58
	System	16 Sep 2020 18:03:58

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:03:49', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '94aa2b7e-2e61-4975-ac8e-233602bd8e5a' User entered '98.0'	System	16 Sep 2020 18:03:58
	System	16 Sep 2020 18:03:58

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:03:52', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '94aa2b7e-2e61-4975-ac8e-233602bd8e5a' User entered 'No (N)'	System	16 Sep 2020 18:03:58
	System	16 Sep 2020 18:03:58

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:03:55', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '94aa2b7e-2e61-4975-ac8e-233602bd8e5a' User entered '16 Sep 2020 13:03'	System	16 Sep 2020 18:03:58
	System	16 Sep 2020 18:03:58

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:07:51



US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 4'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:48:55', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0337a27b-c932-4572-baf4-d3fcf1dd7e74' User entered 'Yes (Y)'	System	17 Sep 2020 17:49:13
	System	17 Sep 2020 17:49:13

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:04', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0337a27b-c932-4572-baf4-d3fcf1dd7e74' User entered '97.5'	System	17 Sep 2020 17:49:13
	System	17 Sep 2020 17:49:13

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:07', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0337a27b-c932-4572-baf4-d3fcf1dd7e74'	System	17 Sep 2020 17:49:13
User entered 'No (N)'	System	17 Sep 2020 17:49:13

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:10', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0337a27b-c932-4572-baf4-d3fcf1dd7e74' User entered '17 Sep 2020 12:49'	System	17 Sep 2020 17:49:13
	System	17 Sep 2020 17:49:13

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 5'	System	14 Sep 2020 18:07:51



US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:37:26', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4a842311-06f4-4457-aafe-5074e4721808'	System	18 Sep 2020 18:38:20
User entered 'Yes (Y)'	System	18 Sep 2020 18:38:20

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:37:37', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4a842311-06f4-4457-aafe-5074e4721808' User entered '98.0'	System	18 Sep 2020 18:38:20
	System	18 Sep 2020 18:38:20

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:37:42', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4a842311-06f4-4457-aafe-5074e4721808'	System	18 Sep 2020 18:38:20
User entered 'No (N)'	System	18 Sep 2020 18:38:20

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:37:45', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4a842311-06f4-4457-aafe-5074e4721808' User entered '18 Sep 2020 13:37'	System	18 Sep 2020 18:38:20
	System	18 Sep 2020 18:38:20

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 6'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:12', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '2436cfb3-2112-4a57-ac3f-cb3104a0bb4f' User entered 'Yes (Y)'	System	20 Sep 2020 13:19:27
	System	20 Sep 2020 13:19:27



US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:19', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '2436cfb3-2112-4a57-ac3f-cb3104a0bb4f' User entered '98.1'	System	20 Sep 2020 13:19:27
	System	20 Sep 2020 13:19:27

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:22', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '2436cfb3-2112-4a57-ac3f-cb3104a0bb4f' User entered 'No (N)'	System	20 Sep 2020 13:19:27
	System	20 Sep 2020 13:19:27

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:24', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '2436cfb3-2112-4a57-ac3f-cb3104a0bb4f' User entered '20 Sep 2020 08:19'	System	20 Sep 2020 13:19:27
	System	20 Sep 2020 13:19:27

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 7'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:09', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '84386e5f-f60b-492d-97e6-b2c990a85ac7' User entered 'Yes (Y)'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:15', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '84386e5f-f60b-492d-97e6-b2c990a85ac7' User entered '97.9'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27



US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:18', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '84386e5f-f60b-492d-97e6-b2c990a85ac7'	System	21 Sep 2020 13:51:27
User entered 'No (N)'	System	21 Sep 2020 13:51:27

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:21', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '84386e5f-f60b-492d-97e6-b2c990a85ac7' User entered '21 Sep 2020 08:51'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:31:48', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5ef8b7a6-38b4-435a-ba7b-2bc9441da760' User entered 'None (1)'	System	14 Sep 2020 18:32:26
	System	14 Sep 2020 18:32:26

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:31:51', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5ef8b7a6-38b4-435a-ba7b-2bc9441da760'	System	14 Sep 2020 18:32:26
User entered 'No (N)'	System	14 Sep 2020 18:32:26

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:31:54', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5ef8b7a6-38b4-435a-ba7b-2bc9441da760'	System	14 Sep 2020 18:32:26
User entered 'No (N)'	System	14 Sep 2020 18:32:26



US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:31:57', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5ef8b7a6-38b4-435a-ba7b-2bc9441da760' User entered 'None (1)'	System	14 Sep 2020 18:32:26
	System	14 Sep 2020 18:32:26

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:32:01', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5ef8b7a6-38b4-435a-ba7b-2bc9441da760' User entered '14 Sep 2020 13:32'	System	14 Sep 2020 18:32:26
	System	14 Sep 2020 18:32:26

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '14 Sep 2020 13:23'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '14 Sep 2020 15:53'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:16', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7b78aecf-8a9a-469b-8b32-f894559bf3c4'	System	14 Sep 2020 23:51:32
User entered 'None (1)'	System	14 Sep 2020 23:51:32

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:20', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7b78aecf-8a9a-469b-8b32-f894559bf3c4'	System	14 Sep 2020 23:51:32
User entered 'No (N)'	System	14 Sep 2020 23:51:32

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:23', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7b78aecf-8a9a-469b-8b32-f894559bf3c4'	System	14 Sep 2020 23:51:32
User entered 'No (N)'	System	14 Sep 2020 23:51:32



US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:26', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7b78aecf-8a9a-469b-8b32-f894559bf3c4'	System	14 Sep 2020 23:51:32
User entered 'None (1)'	System	14 Sep 2020 23:51:32

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:30', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7b78aecf-8a9a-469b-8b32-f894559bf3c4'	System	14 Sep 2020 23:51:32
User entered '14 Sep 2020 18:51'	System	14 Sep 2020 23:51:32

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '14 Sep 2020 16:48'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 2'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:08:40', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6d317ecd-08c2-4c6f-988b-4936d2a64ccd' User entered 'None (1)'	System	15 Sep 2020 17:09:22
	System	15 Sep 2020 17:09:22

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:08:43', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6d317ecd-08c2-4c6f-988b-4936d2a64ccd' User entered 'No (N)'	System	15 Sep 2020 17:09:22
	System	15 Sep 2020 17:09:22

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:08:46', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6d317ecd-08c2-4c6f-988b-4936d2a64ccd' User entered 'No (N)'	System	15 Sep 2020 17:09:22
	System	15 Sep 2020 17:09:22



US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:08:49', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6d317ecd-08c2-4c6f-988b-4936d2a64ccd' User entered 'None (1)'	System	15 Sep 2020 17:09:22
	System	15 Sep 2020 17:09:22

**US3552053**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:08:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:08:54', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6d317ecd-08c2-4c6f-988b-4936d2a64ccd' User entered '15 Sep 2020 12:08'	System	15 Sep 2020 17:09:22
	System	15 Sep 2020 17:09:22

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 3'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6365f167-4b0b-4ebb-a889-ecb74a97804c' User entered 'None (1)'	System	16 Sep 2020 18:04:16
	System	16 Sep 2020 18:04:16

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:04', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6365f167-4b0b-4ebb-a889-ecb74a97804c' User entered 'No (N)'	System	16 Sep 2020 18:04:16
	System	16 Sep 2020 18:04:16

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:07', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6365f167-4b0b-4ebb-a889-ecb74a97804c' User entered 'No (N)'	System	16 Sep 2020 18:04:16
	System	16 Sep 2020 18:04:16



US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:10', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6365f167-4b0b-4ebb-a889-ecb74a97804c' User entered 'None (1)'	System	16 Sep 2020 18:04:16
	System	16 Sep 2020 18:04:16

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:13', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6365f167-4b0b-4ebb-a889-ecb74a97804c' User entered '16 Sep 2020 13:04'	System	16 Sep 2020 18:04:16
	System	16 Sep 2020 18:04:16

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 4'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:13', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f02f9f55-b026-4d18-956c-2f7920db33a4'	System	17 Sep 2020 17:49:27
User entered 'None (1)'	System	17 Sep 2020 17:49:27

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:16', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f02f9f55-b026-4d18-956c-2f7920db33a4' User entered 'No (N)'	System	17 Sep 2020 17:49:27
	System	17 Sep 2020 17:49:27

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:19', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f02f9f55-b026-4d18-956c-2f7920db33a4'	System	17 Sep 2020 17:49:27
User entered 'No (N)'	System	17 Sep 2020 17:49:27



US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:22', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f02f9f55-b026-4d18-956c-2f7920db33a4'	System	17 Sep 2020 17:49:27
User entered 'None (1)'	System	17 Sep 2020 17:49:27

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:24', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f02f9f55-b026-4d18-956c-2f7920db33a4' User entered '17 Sep 2020 12:49'	System	17 Sep 2020 17:49:27
	System	17 Sep 2020 17:49:27

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 5'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:37:51', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd441c37f-f772-414f-8d65-13837d53ba54'	System	18 Sep 2020 18:38:27
User entered 'None (1)'	System	18 Sep 2020 18:38:27

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:37:53', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd441c37f-f772-414f-8d65-13837d53ba54' User entered 'No (N)'	System	18 Sep 2020 18:38:27
	System	18 Sep 2020 18:38:27

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:37:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd441c37f-f772-414f-8d65-13837d53ba54' User entered 'No (N)'	System	18 Sep 2020 18:38:27
	System	18 Sep 2020 18:38:27



US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:37:59', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd441c37f-f772-414f-8d65-13837d53ba54'	System	18 Sep 2020 18:38:27
User entered 'None (1)'	System	18 Sep 2020 18:38:27

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:38:04', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd441c37f-f772-414f-8d65-13837d53ba54' User entered '18 Sep 2020 13:38'	System	18 Sep 2020 18:38:27
	System	18 Sep 2020 18:38:27

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 6'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:18:51', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b248fce1-aaca-4824-90e7-eea3fa5cbf1d'	System	20 Sep 2020 13:19:09
User entered 'None (1)'	System	20 Sep 2020 13:19:09

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:18:55', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b248fce1-aaca-4824-90e7-eea3fa5cbf1d' User entered 'No (N)'	System	20 Sep 2020 13:19:09
	System	20 Sep 2020 13:19:09

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:18:59', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b248fce1-aaca-4824-90e7-eea3fa5cbf1d'	System	20 Sep 2020 13:19:09
User entered 'No (N)'	System	20 Sep 2020 13:19:09



US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:03', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b248fce1-aaca-4824-90e7-eea3fa5cbf1d'	System	20 Sep 2020 13:19:09
User entered 'None (1)'	System	20 Sep 2020 13:19:09

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:05', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b248fce1-aaca-4824-90e7-eea3fa5cbf1d' User entered '20 Sep 2020 08:19'	System	20 Sep 2020 13:19:09
	System	20 Sep 2020 13:19:09

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 7'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:25', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '07a3ddc6-e489-4acb-af31-e7a3333ffd1c'	System	21 Sep 2020 13:51:39
User entered 'None (1)'	System	21 Sep 2020 13:51:39

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:28', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '07a3ddc6-e489-4acb-af31-e7a3333ffd1c' User entered 'No (N)'	System	21 Sep 2020 13:51:39
	System	21 Sep 2020 13:51:39

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:30', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '07a3ddc6-e489-4acb-af31-e7a3333ffd1c' User entered 'No (N)'	System	21 Sep 2020 13:51:39
	System	21 Sep 2020 13:51:39



US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:33', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '07a3ddc6-e489-4acb-af31-e7a3333ffd1c' User entered 'None (1)'	System	21 Sep 2020 13:51:39
	System	21 Sep 2020 13:51:39

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '07a3ddc6-e489-4acb-af31-e7a3333ffd1c' User entered '21 Sep 2020 08:51'	System	21 Sep 2020 13:51:39
	System	21 Sep 2020 13:51:39

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:32:05', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b64e00bc-a906-4b11-b22b-84d6f0f88b23' User entered 'None (0)'	System	14 Sep 2020 18:32:42
	System	14 Sep 2020 18:32:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:32:07', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b64e00bc-a906-4b11-b22b-84d6f0f88b23' User entered 'None (0)'	System	14 Sep 2020 18:32:42
	System	14 Sep 2020 18:32:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:32:10', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b64e00bc-a906-4b11-b22b-84d6f0f88b23' User entered 'None (0)'	System	14 Sep 2020 18:32:42
	System	14 Sep 2020 18:32:42



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:32:12', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b64e00bc-a906-4b11-b22b-84d6f0f88b23' User entered 'None (0)'	System	14 Sep 2020 18:32:42
	System	14 Sep 2020 18:32:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:32:15', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b64e00bc-a906-4b11-b22b-84d6f0f88b23' User entered 'None (0)'	System	14 Sep 2020 18:32:42
	System	14 Sep 2020 18:32:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:32:18', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b64e00bc-a906-4b11-b22b-84d6f0f88b23' User entered 'None (0)'	System	14 Sep 2020 18:32:42
	System	14 Sep 2020 18:32:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:32:21', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b64e00bc-a906-4b11-b22b-84d6f0f88b23'	System	14 Sep 2020 18:32:42
User entered 'No (N)'	System	14 Sep 2020 18:32:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T13:32:24', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b64e00bc-a906-4b11-b22b-84d6f0f88b23' User entered '14 Sep 2020 13:32'	System	14 Sep 2020 18:32:42
	System	14 Sep 2020 18:32:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '14 Sep 2020 13:23'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '14 Sep 2020 15:53'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 18:07:51



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:34', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'a93eb263-df6a-4527-949b-fbb70aac8480' User entered 'None (0)'	System	14 Sep 2020 23:51:56
	System	14 Sep 2020 23:51:56

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'a93eb263-df6a-4527-949b-fbb70aac8480' User entered 'None (0)'	System	14 Sep 2020 23:51:56
	System	14 Sep 2020 23:51:56

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:38', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'a93eb263-df6a-4527-949b-fbb70aac8480' User entered 'None (0)'	System	14 Sep 2020 23:51:56
	System	14 Sep 2020 23:51:56

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:40', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'a93eb263-df6a-4527-949b-fbb70aac8480' User entered 'None (0)'	System	14 Sep 2020 23:51:56
	System	14 Sep 2020 23:51:56

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:44', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'a93eb263-df6a-4527-949b-fbb70aac8480' User entered 'None (0)'	System	14 Sep 2020 23:51:56
	System	14 Sep 2020 23:51:56

**US3552053**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:46', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'a93eb263-df6a-4527-949b-fbb70aac8480' User entered 'None (0)'	System	14 Sep 2020 23:51:56
	System	14 Sep 2020 23:51:56

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:48', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'a93eb263-df6a-4527-949b-fbb70aac8480' User entered 'No (N)'	System	14 Sep 2020 23:51:56
	System	14 Sep 2020 23:51:56

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-14T18:51:51', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'a93eb263-df6a-4527-949b-fbb70aac8480' User entered '14 Sep 2020 18:51'	System	14 Sep 2020 23:51:56
	System	14 Sep 2020 23:51:56



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '14 Sep 2020 16:48'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 2'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:09:08', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '16241e1c-e19e-4194-9580-c486e874406c'	System	15 Sep 2020 17:09:57
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Sep 2020 17:09:57

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:09:15', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '16241e1c-e19e-4194-9580-c486e874406c' User entered 'Significant; prevents daily activity (3)'	System	15 Sep 2020 17:09:57
	System	15 Sep 2020 17:09:57

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:09:20', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '16241e1c-e19e-4194-9580-c486e874406c' User entered 'Some interference with activity (2)'	System	15 Sep 2020 17:09:57
	System	15 Sep 2020 17:09:57

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:09:26', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '16241e1c-e19e-4194-9580-c486e874406c' User entered 'Some interference with activity (2)'	System	15 Sep 2020 17:09:57
	System	15 Sep 2020 17:09:57

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:09:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '16241e1c-e19e-4194-9580-c486e874406c'	System	15 Sep 2020 17:09:57
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	15 Sep 2020 17:09:57



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:09:45', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '16241e1c-e19e-4194-9580-c486e874406c'	System	15 Sep 2020 17:09:57
User entered 'Some interference with activity not requiring medical attention (2)'	System	15 Sep 2020 17:09:57

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:09:48', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '16241e1c-e19e-4194-9580-c486e874406c' User entered 'No (N)'	System	15 Sep 2020 17:09:57
	System	15 Sep 2020 17:09:57

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-15T12:09:53', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '16241e1c-e19e-4194-9580-c486e874406c' User entered '15 Sep 2020 12:09'	System	15 Sep 2020 17:09:57
	System	15 Sep 2020 17:09:57

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 3'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:22', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '179b93ed-52bf-4d7c-ab11-85e4d0c9f7f4'	System	16 Sep 2020 18:05:01
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	16 Sep 2020 18:05:01

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:26', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '179b93ed-52bf-4d7c-ab11-85e4d0c9f7f4'	System	16 Sep 2020 18:05:01
User entered 'Some interference with activity (2)'	System	16 Sep 2020 18:05:01



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:32', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '179b93ed-52bf-4d7c-ab11-85e4d0c9f7f4'	System	16 Sep 2020 18:05:01
User entered 'No interference with activity (1)'	System	16 Sep 2020 18:05:01

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '179b93ed-52bf-4d7c-ab11-85e4d0c9f7f4'	System	16 Sep 2020 18:05:01
User entered 'No interference with activity (1)'	System	16 Sep 2020 18:05:01

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:48', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '179b93ed-52bf-4d7c-ab11-85e4d0c9f7f4'	System	16 Sep 2020 18:05:01
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	16 Sep 2020 18:05:01

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:52', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '179b93ed-52bf-4d7c-ab11-85e4d0c9f7f4'	System	16 Sep 2020 18:05:01
User entered 'No interference with activity (1)'	System	16 Sep 2020 18:05:01

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '179b93ed-52bf-4d7c-ab11-85e4d0c9f7f4'	System	16 Sep 2020 18:05:01
User entered 'No (N)'	System	16 Sep 2020 18:05:01

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-16T13:04:59', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '179b93ed-52bf-4d7c-ab11-85e4d0c9f7f4' User entered '16 Sep 2020 13:04'	System	16 Sep 2020 18:05:01
	System	16 Sep 2020 18:05:01

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:07:51



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 4'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:32', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '74b1ecda-7ef0-4379-84cf-3f33324916d9'	System	17 Sep 2020 17:50:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	17 Sep 2020 17:50:09

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '74b1ecda-7ef0-4379-84cf-3f33324916d9'	System	17 Sep 2020 17:50:09
User entered 'Some interference with activity (2)'	System	17 Sep 2020 17:50:09

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:40', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '74b1ecda-7ef0-4379-84cf-3f33324916d9'	System	17 Sep 2020 17:50:09
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:50:09

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:43', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '74b1ecda-7ef0-4379-84cf-3f33324916d9'	System	17 Sep 2020 17:50:09
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:50:09

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:49', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '74b1ecda-7ef0-4379-84cf-3f33324916d9'	System	17 Sep 2020 17:50:09
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	17 Sep 2020 17:50:09

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:49:54', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '74b1ecda-7ef0-4379-84cf-3f33324916d9' User entered 'None (0)'	System	17 Sep 2020 17:50:09
	System	17 Sep 2020 17:50:09

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:50:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '74b1ecda-7ef0-4379-84cf-3f33324916d9'	System	17 Sep 2020 17:50:09
User entered 'Yes (Y)'	System	17 Sep 2020 17:50:09



**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-17T12:50:03', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '74b1ecda-7ef0-4379-84cf-3f33324916d9' User entered '17 Sep 2020 12:50'	System	17 Sep 2020 17:50:09
	System	17 Sep 2020 17:50:09

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 5'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:38:13', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'de4c13b3-3c8c-4319-8962-95979719ffb5'	System	18 Sep 2020 18:38:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	18 Sep 2020 18:38:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:38:17', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'de4c13b3-3c8c-4319-8962-95979719ffb5'	System	18 Sep 2020 18:38:42
User entered 'Some interference with activity (2)'	System	18 Sep 2020 18:38:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:38:22', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'de4c13b3-3c8c-4319-8962-95979719ffb5'	System	18 Sep 2020 18:38:42
User entered 'No interference with activity (1)'	System	18 Sep 2020 18:38:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:38:24', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'de4c13b3-3c8c-4319-8962-95979719ffb5'	System	18 Sep 2020 18:38:42
User entered 'No interference with activity (1)'	System	18 Sep 2020 18:38:42



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:38:29', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'de4c13b3-3c8c-4319-8962-95979719ffb5'	System	18 Sep 2020 18:38:42
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	18 Sep 2020 18:38:42

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:38:33', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'de4c13b3-3c8c-4319-8962-95979719ffb5'	System	18 Sep 2020 18:38:42
User entered 'No interference with activity (1)'	System	18 Sep 2020 18:38:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:38:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'de4c13b3-3c8c-4319-8962-95979719ffb5'	System	18 Sep 2020 18:38:42
User entered 'Yes (Y)'	System	18 Sep 2020 18:38:42

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-18T13:38:39', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'de4c13b3-3c8c-4319-8962-95979719ffb5' User entered '18 Sep 2020 13:38'	System	18 Sep 2020 18:38:42
	System	18 Sep 2020 18:38:42

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 6'	System	14 Sep 2020 18:07:51

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:30', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7411fd0c-ecda-4a07-af33-3d552bf52ecf' User entered 'No interference with activity (1)'	System	20 Sep 2020 13:20:00
	System	20 Sep 2020 13:20:00



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:35', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7411fd0c-ecda-4a07-af33-3d552bf52ecf' User entered 'No interference with activity (1)'	System	20 Sep 2020 13:20:00
	System	20 Sep 2020 13:20:00

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:39', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7411fd0c-ecda-4a07-af33-3d552bf52ecf' User entered 'No interference with activity (1)'	System	20 Sep 2020 13:20:00
	System	20 Sep 2020 13:20:00

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:43', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7411fd0c-ecda-4a07-af33-3d552bf52ecf' User entered 'None (0)'	System	20 Sep 2020 13:20:00
	System	20 Sep 2020 13:20:00

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:47', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7411fd0c-ecda-4a07-af33-3d552bf52ecf'	System	20 Sep 2020 13:20:00
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Sep 2020 13:20:00

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:50', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7411fd0c-ecda-4a07-af33-3d552bf52ecf' User entered 'None (0)'	System	20 Sep 2020 13:20:00
	System	20 Sep 2020 13:20:00

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:53', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7411fd0c-ecda-4a07-af33-3d552bf52ecf' User entered 'No (N)'	System	20 Sep 2020 13:20:00
	System	20 Sep 2020 13:20:00

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-20T08:19:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '7411fd0c-ecda-4a07-af33-3d552bf52ecf' User entered '20 Sep 2020 08:19'	System	20 Sep 2020 13:20:00
	System	20 Sep 2020 13:20:00

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 18:07:51



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	14 Sep 2020 18:07:51
User entered 'Day 7'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:40', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '47320e02-f81e-4180-b907-08422c78739a' User entered 'None (0)'	System	21 Sep 2020 13:52:03
	System	21 Sep 2020 13:52:03

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:44', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '47320e02-f81e-4180-b907-08422c78739a' User entered 'None (0)'	System	21 Sep 2020 13:52:03
	System	21 Sep 2020 13:52:03

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:47', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '47320e02-f81e-4180-b907-08422c78739a' User entered 'None (0)'	System	21 Sep 2020 13:52:03
	System	21 Sep 2020 13:52:03

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:50', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '47320e02-f81e-4180-b907-08422c78739a' User entered 'None (0)'	System	21 Sep 2020 13:52:03
	System	21 Sep 2020 13:52:03

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:53', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '47320e02-f81e-4180-b907-08422c78739a' User entered 'None (0)'	System	21 Sep 2020 13:52:03
	System	21 Sep 2020 13:52:03

**US3552053**

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

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

**Generated On: 10 Jun 2021 08:08:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:55', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '47320e02-f81e-4180-b907-08422c78739a' User entered 'None (0)'	System	21 Sep 2020 13:52:03
	System	21 Sep 2020 13:52:03



US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:51:58', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '47320e02-f81e-4180-b907-08422c78739a' User entered 'No (N)'	System	21 Sep 2020 13:52:03
	System	21 Sep 2020 13:52:03

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-09-21T08:52:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '47320e02-f81e-4180-b907-08422c78739a' User entered '21 Sep 2020 08:52'	System	21 Sep 2020 13:52:03
	System	21 Sep 2020 13:52:03

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 18:07:51

US3552053

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:08:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 18:07:51

US3552053

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:02:39

US3552053

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:02:39

US3552053

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:02:39

US3552053

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4)	21 Sep 2020 14:02:39



US3552053

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 15:01:41

US3552053

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User entered 'l'	System	28 Sep 2020 15:01:41

US3552053

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 15:01:50

US3552053

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '28 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 15:01:50

US3552053

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 15:01:50

US3552053

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4)	28 Sep 2020 15:01:50

US3552053

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 16:09:05

**US3552053**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:08:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User entered 'l'	System	05 Oct 2020 16:09:05



US3552053

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 16:09:13

US3552053

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '05 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:27:43
User entered '5 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 16:09:13

US3552053

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 16:09:13

US3552053

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 16:09:13

US3552053

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:04:31

**US3552053**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:08:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:56
User entered 'I'	System	12 Oct 2020 18:04:31

US3552053

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:04:41

US3552053

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '12 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:04:41



US3552053

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:04:41

**US3552053**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:08:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'VISIT3'	System	12 Oct 2020 18:04:41

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:24:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '12 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:24:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '11:36' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:24:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:04:47

**US3552053**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:08:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '12 Oct 2020 11:36'	System	12 Oct 2020 18:24:45
User entered empty.	System	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '97.2' F reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:24:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:24:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:04:47



US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '57' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:24:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:04:47

**US3552053**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:08:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'bpm'	System	12 Oct 2020 18:24:45
User entered empty.	System	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '16' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:24:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'breaths/min'	System	12 Oct 2020 18:24:45
User entered empty.	System	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '130' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:24:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	12 Oct 2020 18:24:45
User entered empty.	System	12 Oct 2020 18:04:47

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '80' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:24:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:04:47



US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'mmHg'	System	12 Oct 2020 18:24:45
User entered empty.	System	12 Oct 2020 18:04:47

**US3552053**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:08:15**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57

US3552053

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57

US3552053

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:04:53

US3552053

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:04:53

US3552053

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:05:09

US3552053

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:37:06
User entered '12 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:05:09

US3552053

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered '12:05' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 18:26:20
User entered '12:15'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:05:09



US3552053

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered '12 Oct 2020 12:05'	System	12 Oct 2020 18:26:20
User entered '12 Oct 2020 12:15'	System	12 Oct 2020 18:05:09

US3552053

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:37:06
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 21:05:41

**US3552053**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:08:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'I'	System	12 Nov 2020 21:05:41

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 64'	System	17 Aug 2020 18:43:49

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-10-19T16:55:51', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '75628f03-d5b4-40e1-b115-fa1038668dc1' User entered 'No (N)'	System	19 Oct 2020 21:56:06
	System	19 Oct 2020 21:56:06

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-10-19T16:55:57', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '75628f03-d5b4-40e1-b115-fa1038668dc1'	System	19 Oct 2020 21:56:06
User entered 'No (N)'	System	19 Oct 2020 21:56:06

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-10-19T16:56:03', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '75628f03-d5b4-40e1-b115-fa1038668dc1' User entered '19 Oct 2020 16:56:03'	System	19 Oct 2020 21:56:06
	System	19 Oct 2020 21:56:06

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 18:43:49



US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 71'	System	17 Aug 2020 18:43:49

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-10-24T10:27:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '65835b6f-b90b-448a-8bf3-a639e7764500'	System	24 Oct 2020 15:28:30
User entered 'No (N)'	System	24 Oct 2020 15:28:30

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-10-24T10:28:21', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '65835b6f-b90b-448a-8bf3-a639e7764500'	System	24 Oct 2020 15:28:30
User entered 'No (N)'	System	24 Oct 2020 15:28:30

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-10-24T10:28:28', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '65835b6f-b90b-448a-8bf3-a639e7764500' User entered '24 Oct 2020 10:28:28'	System	24 Oct 2020 15:28:30
	System	24 Oct 2020 15:28:30

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 18:43:49

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 78'	System	17 Aug 2020 18:43:49



US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-02T11:19:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0f213a16-ce51-4a3f-8051-d9c26c67ee2c'	System	02 Nov 2020 17:20:07
User entered 'No (N)'	System	02 Nov 2020 17:20:07

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-02T11:19:59', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0f213a16-ce51-4a3f-8051-d9c26c67ee2c'	System	02 Nov 2020 17:20:07
User entered 'No (N)'	System	02 Nov 2020 17:20:07

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-02T11:20:03', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0f213a16-ce51-4a3f-8051-d9c26c67ee2c' User entered '02 Nov 2020 11:20:03'	System	02 Nov 2020 17:20:07
	System	02 Nov 2020 17:20:07

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 18:43:49

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 18:43:49

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered 'Day 92'	System	17 Aug 2020 18:43:49

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-14T22:13:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '10df2e2c-ce86-4498-a857-4f0ae3168b77'	System	15 Nov 2020 04:14:09
User entered 'No (N)'	System	15 Nov 2020 04:14:09

US3552053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-14T22:14:01', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '10df2e2c-ce86-4498-a857-4f0ae3168b77'	System	15 Nov 2020 04:14:09
User entered 'No (N)'	System	15 Nov 2020 04:14:09



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-14T22:14:05', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '10df2e2c-ce86-4498-a857-4f0ae3168b77' User entered '14 Nov 2020 22:14:05'	System	15 Nov 2020 04:14:09
	System	15 Nov 2020 04:14:09

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 18:43:49

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:53:56
Data entry locked.	System	17 Aug 2020 18:43:49
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 18:43:49

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-21T08:13:30', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd4dabfcd-b5db-4823-a99a-12d7557c890b'	System	21 Nov 2020 14:13:49
User entered 'No (N)'	System	21 Nov 2020 14:13:49

US3552053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:15

Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-21T08:13:37', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd4dabfcd-b5db-4823-a99a-12d7557c890b'	System	21 Nov 2020 14:13:49
User entered 'No (N)'	System	21 Nov 2020 14:13:49

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-21T08:13:45', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'd4dabfcd-b5db-4823-a99a-12d7557c890b' User entered '21 Nov 2020 08:13:45'	System	21 Nov 2020 14:13:49
	System	21 Nov 2020 14:13:49

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-26T19:00:46', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '388324e6-90f6-4df9-b06b-aae3077812d7' User entered 'No (N)'	System	27 Nov 2020 01:01:06

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-26T19:00:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '388324e6-90f6-4df9-b06b-aae3077812d7'	System	27 Nov 2020 01:01:06
User entered 'No (N)'	System	27 Nov 2020 01:01:06

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-11-26T19:01:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '388324e6-90f6-4df9-b06b-aae3077812d7' User entered '26 Nov 2020 19:01:00'	System	27 Nov 2020 01:01:06
	System	27 Nov 2020 01:01:06

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:29:50



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-02T16:42:23', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '690234f5-8274-48a8-a027-ed28d7cf67ab' User entered 'No (N)'	System	02 Dec 2020 22:42:40
	System	02 Dec 2020 22:42:40

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-02T16:42:34', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '690234f5-8274-48a8-a027-ed28d7cf67ab' User entered 'No (N)'	System	02 Dec 2020 22:42:40

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-02T16:42:37', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '690234f5-8274-48a8-a027-ed28d7cf67ab' User entered '02 Dec 2020 16:42:37'	System	02 Dec 2020 22:42:40
	System	02 Dec 2020 22:42:40

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-09T14:02:44', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '49f99d2d-dfaf-458f-ba8f-baa21a4ab7c1'	System	09 Dec 2020 20:04:38
User entered 'No (N)'	System	09 Dec 2020 20:04:38

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-09T14:04:24', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '49f99d2d-dfaf-458f-ba8f-baa21a4ab7c1' User entered 'No (N)'	System	09 Dec 2020 20:04:38



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-09T14:04:31', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '49f99d2d-dfaf-458f-ba8f-baa21a4ab7c1' User entered '09 Dec 2020 14:04:31'	System	09 Dec 2020 20:04:38
	System	09 Dec 2020 20:04:38

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-16T09:22:44', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4e62c661-e343-421b-9e6b-03627946defb' User entered 'No (N)'	System	16 Dec 2020 15:22:57
	System	16 Dec 2020 15:22:57

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-16T09:22:48', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4e62c661-e343-421b-9e6b-03627946defb' User entered 'No (N)'	System	16 Dec 2020 15:22:57

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-16T09:22:52', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4e62c661-e343-421b-9e6b-03627946defb' User entered '16 Dec 2020 09:22:52'	System	16 Dec 2020 15:22:57
	System	16 Dec 2020 15:22:57

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-23T08:28:21', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'bf9e4374-58bd-4353-8308-3270d130235e' User entered 'No (N)'	System	23 Dec 2020 14:28:31
	System	23 Dec 2020 14:28:31

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-23T08:28:25', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'bf9e4374-58bd-4353-8308-3270d130235e' User entered 'No (N)'	System	23 Dec 2020 14:28:31
	System	23 Dec 2020 14:28:31

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-23T08:28:29', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'bf9e4374-58bd-4353-8308-3270d130235e' User entered '23 Dec 2020 08:28:29'	System	23 Dec 2020 14:28:31
	System	23 Dec 2020 14:28:31

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:29:50



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-30T08:13:08', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ded02568-7667-47c4-ace4-89a4f044651c' User entered 'No (N)'	System	30 Dec 2020 14:13:37
	System	30 Dec 2020 14:13:37

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-30T08:13:11', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ded02568-7667-47c4-ace4-89a4f044651c' User entered 'Yes (Y)'	System	30 Dec 2020 14:13:37
	System	30 Dec 2020 14:13:37

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Please 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-30T08:13:16', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ded02568-7667-47c4-ace4-89a4f044651c'	System	30 Dec 2020 14:13:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 14:13:37

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2020-12-30T08:13:27', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ded02568-7667-47c4-ace4-89a4f044651c' User entered '30 Dec 2020 08:13:27'	System	30 Dec 2020 14:13:37
	System	30 Dec 2020 14:13:37

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-06T10:31:57', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'e6fe2cf4-3ec3-431d-802a-fbc9ea49e753'	System	06 Jan 2021 16:32:12
User entered 'No (N)'	System	06 Jan 2021 16:32:12



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-06T10:32:03', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'e6fe2cf4-3ec3-431d-802a-fbc9ea49e753'	System	06 Jan 2021 16:32:12
User entered 'No (N)'	System	06 Jan 2021 16:32:12

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-06T10:32:06', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'e6fe2cf4-3ec3-431d-802a-fbc9ea49e753' User entered '06 Jan 2021 10:32:06'	System	06 Jan 2021 16:32:12
	System	06 Jan 2021 16:32:12

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-15T17:15:53', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b1e41984-1a09-4c38-80a6-9e496635c8d9' User entered 'No (N)'	System	15 Jan 2021 23:16:02
	System	15 Jan 2021 23:16:02

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-15T17:15:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b1e41984-1a09-4c38-80a6-9e496635c8d9' User entered 'No (N)'	System	15 Jan 2021 23:16:02

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-15T17:15:59', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'b1e41984-1a09-4c38-80a6-9e496635c8d9' User entered '15 Jan 2021 17:15:59'	System	15 Jan 2021 23:16:02



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-20T06:14:30', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f7650568-6206-4f4d-ac07-d3a6578b13a0'	System	20 Jan 2021 12:14:39
User entered 'No (N)'	System	20 Jan 2021 12:14:39

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-20T06:14:32', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f7650568-6206-4f4d-ac07-d3a6578b13a0'	System	20 Jan 2021 12:14:39
User entered 'No (N)'	System	20 Jan 2021 12:14:39

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-20T06:14:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f7650568-6206-4f4d-ac07-d3a6578b13a0' User entered '20 Jan 2021 06:14:36'	System	20 Jan 2021 12:14:39
	System	20 Jan 2021 12:14:39

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-28T14:33:33', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6b8d38eb-71d4-4cab-93fb-fc5ed02ca64d'	System	28 Jan 2021 20:33:43
User entered 'No (N)'	System	28 Jan 2021 20:33:43

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-28T14:33:36', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6b8d38eb-71d4-4cab-93fb-fc5ed02ca64d' User entered 'No (N)'	System	28 Jan 2021 20:33:43
	System	28 Jan 2021 20:33:43

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-01-28T14:33:41', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '6b8d38eb-71d4-4cab-93fb-fc5ed02ca64d' User entered '28 Jan 2021 14:33:41'	System	28 Jan 2021 20:33:43
	System	28 Jan 2021 20:33:43

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-03T16:37:01', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ce4b9468-b845-4c74-8b47-e44bbbbbfeeb1' User entered 'No (N)'	System	03 Feb 2021 22:37:13
	System	03 Feb 2021 22:37:13



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-03T16:37:06', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ce4b9468-b845-4c74-8b47-e44bbbbfeeb1' User entered 'No (N)'	System	03 Feb 2021 22:37:13

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-03T16:37:09', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ce4b9468-b845-4c74-8b47-e44bbbbfeeb1' User entered '03 Feb 2021 16:37:09'	System	03 Feb 2021 22:37:13
	System	03 Feb 2021 22:37:13

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-10T18:29:52', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '19320a0c-473b-457b-8380-226c2398a130'	System	11 Feb 2021 00:30:07
User entered 'No (N)'	System	11 Feb 2021 00:30:07

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-10T18:29:56', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '19320a0c-473b-457b-8380-226c2398a130'	System	11 Feb 2021 00:30:07
User entered 'No (N)'	System	11 Feb 2021 00:30:07

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-10T18:30:01', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '19320a0c-473b-457b-8380-226c2398a130'	System	11 Feb 2021 00:30:07
User entered '10 Feb 2021 18:30:01'	System	11 Feb 2021 00:30:07



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-19T08:06:31', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ceacf646-d704-424a-b69a-27f3b3c50c16'	System	19 Feb 2021 14:06:42
User entered 'No (N)'	System	19 Feb 2021 14:06:42

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-19T08:06:34', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ceacf646-d704-424a-b69a-27f3b3c50c16'	System	19 Feb 2021 14:06:42
User entered 'No (N)'	System	19 Feb 2021 14:06:42

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-19T08:06:40', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ceacf646-d704-424a-b69a-27f3b3c50c16'	System	19 Feb 2021 14:06:42
User entered '19 Feb 2021 08:06:40'	System	19 Feb 2021 14:06:42

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-24T17:28:03-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ccb9dec0-48bf-4288-8266-8b3133c43b66'	System	24 Feb 2021 23:34:36
User entered 'No (N)'	System	24 Feb 2021 23:34:36

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-24T17:28:06-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ccb9dec0-48bf-4288-8266-8b3133c43b66'	System	24 Feb 2021 23:34:36
User entered 'No (N)'	System	24 Feb 2021 23:34:36

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-02-24T17:28:11-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'ccb9dec0-48bf-4288-8266-8b3133c43b66'	System	24 Feb 2021 23:34:36
User entered '24 Feb 2021 23:28:11'	System	24 Feb 2021 23:34:36

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-05T06:18:43-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4710836a-7098-4c21-b5b1-6bd04850c111'	System	05 Mar 2021 12:18:53
User entered 'No (N)'	System	05 Mar 2021 12:18:53



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-05T06:18:47-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4710836a-7098-4c21-b5b1-6bd04850c111'	System	05 Mar 2021 12:18:53
User entered 'No (N)'	System	05 Mar 2021 12:18:53

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-05T06:18:51-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4710836a-7098-4c21-b5b1-6bd04850c111'	System	05 Mar 2021 12:18:53
User entered '05 Mar 2021 06:18:51'	System	05 Mar 2021 12:18:53

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-10T15:57:39-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '890ed3db-6997-4faf-8c16-a7cfd1f3a99e'	System	10 Mar 2021 21:57:49
User entered 'No (N)'	System	10 Mar 2021 21:57:49

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-10T15:57:42-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '890ed3db-6997-4faf-8c16-a7cfd1f3a99e'	System	10 Mar 2021 21:57:49
User entered 'No (N)'	System	10 Mar 2021 21:57:49

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-10T15:57:45-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '890ed3db-6997-4faf-8c16-a7cfd1f3a99e' User entered '10 Mar 2021 15:57:45'	System	10 Mar 2021 21:57:49
	System	10 Mar 2021 21:57:49



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-17T14:00:03-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0bd2ff82-b483-4a99-a8f9-9c47476c7aee'	System	17 Mar 2021 19:00:10
User entered 'No (N)'	System	17 Mar 2021 19:00:10

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-17T14:00:05-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0bd2ff82-b483-4a99-a8f9-9c47476c7aee'	System	17 Mar 2021 19:00:10
User entered 'No (N)'	System	17 Mar 2021 19:00:10

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-17T14:00:08-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '0bd2ff82-b483-4a99-a8f9-9c47476c7aee'	System	17 Mar 2021 19:00:10
User entered '17 Mar 2021 14:00:08'	System	17 Mar 2021 19:00:10

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:29:50

**US3552053**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-24T06:29:06-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f79fbeb7-cdea-4288-93f1-9c8e2c971063'	System	24 Mar 2021 11:29:15
User entered 'No (N)'	System	24 Mar 2021 11:29:15

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-24T06:29:09-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f79fbeb7-cdea-4288-93f1-9c8e2c971063'	System	24 Mar 2021 11:29:15
User entered 'No (N)'	System	24 Mar 2021 11:29:15

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-24T06:29:13-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'f79fbeb7-cdea-4288-93f1-9c8e2c971063'	System	24 Mar 2021 11:29:15
User entered '24 Mar 2021 06:29:13'	System	24 Mar 2021 11:29:15

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-31T05:28:13-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '83428f41-8003-4abc-8704-69c6ff658736'	System	31 Mar 2021 10:28:22
User entered 'No (N)'	System	31 Mar 2021 10:28:22



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-31T05:28:15-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '83428f41-8003-4abc-8704-69c6ff658736'	System	31 Mar 2021 10:28:22
User entered 'No (N)'	System	31 Mar 2021 10:28:22

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-31T05:28:18-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '83428f41-8003-4abc-8704-69c6ff658736'	System	31 Mar 2021 10:28:22
User entered '31 Mar 2021 05:28:18'	System	31 Mar 2021 10:28:22

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-07T08:38:01-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5ad9b7ab-a5b3-430f-8916-e8035dacd02d' User entered 'No (N)'	System	07 Apr 2021 13:38:14
	System	07 Apr 2021 13:38:14

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-07T08:38:04-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5ad9b7ab-a5b3-430f-8916-e8035dacd02d' User entered 'No (N)'	System	07 Apr 2021 13:38:14

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-07T08:38:08-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '5ad9b7ab-a5b3-430f-8916-e8035dacd02d' User entered '07 Apr 2021 08:38:08'	System	07 Apr 2021 13:38:14
	System	07 Apr 2021 13:38:14



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-14T08:09:56-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'cf158456-a32e-4bd7-9c1c-678abb20c7ac'	System	14 Apr 2021 13:10:07
User entered 'No (N)'	System	14 Apr 2021 13:10:07

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-14T08:09:58-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'cf158456-a32e-4bd7-9c1c-678abb20c7ac'	System	14 Apr 2021 13:10:07
User entered 'No (N)'	System	14 Apr 2021 13:10:07

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-14T08:10:01-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: 'cf158456-a32e-4bd7-9c1c-678abb20c7ac'	System	14 Apr 2021 13:10:07
User entered '14 Apr 2021 08:10:01'	System	14 Apr 2021 13:10:07

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-21T10:05:27-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '853b1298-edd1-4f47-a45a-38c4d34719cf' User entered 'No (N)'	System	21 Apr 2021 15:05:41
	System	21 Apr 2021 15:05:41

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-21T10:05:34-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '853b1298-edd1-4f47-a45a-38c4d34719cf' User entered 'No (N)'	System	21 Apr 2021 15:05:41

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-21T10:05:38-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '853b1298-edd1-4f47-a45a-38c4d34719cf' User entered '21 Apr 2021 10:05:38'	System	21 Apr 2021 15:05:41
	System	21 Apr 2021 15:05:41

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-29T07:28:30-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '83cb87e2-bcf7-49a9-978f-fa575249a273'	System	29 Apr 2021 12:28:44
User entered 'No (N)'	System	29 Apr 2021 12:28:44



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

Have you been exposed to someone with 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 (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-29T07:28:32-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '83cb87e2-bcf7-49a9-978f-fa575249a273'	System	29 Apr 2021 12:28:44
User entered 'No (N)'	System	29 Apr 2021 12:28:44

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-04-29T07:28:36-05:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '83cb87e2-bcf7-49a9-978f-fa575249a273'	System	29 Apr 2021 12:28:44
User entered '29 Apr 2021 07:28:36'	System	29 Apr 2021 12:28:44

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:29:50



**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:29:50

**US3552053**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:08:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:29:50
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:29:50

US3552053

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:08:15**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-05T06:18:59-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4a630288-1f8f-4406-9310-8cc5f7935c7d'	System	05 Mar 2021 12:19:24
User entered 'Yes (Y)'	System	05 Mar 2021 12:19:24

US3552053

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:08:15**

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-05T06:19:07-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4a630288-1f8f-4406-9310-8cc5f7935c7d' User entered 'No (N)'	System	05 Mar 2021 12:19:24
	System	05 Mar 2021 12:19:24

**US3552053**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:02:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082E2B92-52E0-413A-9D36-87256F54375A)', Time: '2021-03-05T06:19:15-06:00', User OID: 'PatientReportedOutcome (US3552053)', ODM File OID: '4a630288-1f8f-4406-9310-8cc5f7935c7d' User entered '05 Mar 2021 06:19:15'	System	05 Mar 2021 12:19:24
	System	05 Mar 2021 12:19:24

US3552053

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 21:05:49

US3552053

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered '10 Nov 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	13 Nov 2020 17:04:59
User entered '12 Nov 2020'	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 21:05:49



US3552053

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 21:05:49

US3552053

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	12 Nov 2020 21:05:49

US3552053

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	10 Dec 2020 16:24:31

**US3552053**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:08:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:38:57
User entered 'l'	System	10 Dec 2020 16:24:31

**US3552053**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:08:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	10 Dec 2020 16:24:40

US3552053

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10 Dec 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	10 Dec 2020 16:24:40

US3552053

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4)	10 Dec 2020 16:24:40

US3552053

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4)	10 Dec 2020 16:24:40



US3552053

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 18:35:53

**US3552053**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:08:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered 'l'	System	12 Jan 2021 18:35:53

US3552053

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 18:36:02

US3552053

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '12 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 18:36:02

US3552053

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 18:36:02

US3552053

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4)	12 Jan 2021 18:36:02

US3552053

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Feb 2021 15:20:18

**US3552053**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:08:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered 'l'	System	11 Feb 2021 15:20:18



**US3552053**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:08:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Feb 2021 15:20:27

US3552053

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '11 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Feb 2021 15:20:27

US3552053

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Feb 2021 15:20:27

US3552053

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4)	11 Feb 2021 15:20:27

US3552053

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	11 Feb 2021 21:22:12

**US3552053**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:08:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered 'l'	System	11 Feb 2021 21:22:12

US3552053

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 18:48:28

US3552053

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered '01 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 18:48:28



US3552053

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 18:48:28

**US3552053**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:08:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered 'VISIT4'	System	01 Mar 2021 18:48:28

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:19:04
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:19:04
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:19:04
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered empty.	System	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:19:04
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:19:04
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:31:04



US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:19:04
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:19:04
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered empty.	System	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:19:04
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered empty.	System	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:19:04
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered empty.	System	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:19:04
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:31:04



US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered empty.	System	30 Mar 2021 14:31:04

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02

US3552053

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02

US3552053

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:19:04
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 14:30:57
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	30 Mar 2021 14:30:57
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
	(b) (4)	
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	01 Mar 2021 18:48:41
	(b) (4)	

US3552053

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:19:04
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Mar 2021 14:30:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	30 Mar 2021 14:30:57
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
	(b) (4)	
User entered '01 Mar 2021'	Stanley Doublin (b) (4)	01 Mar 2021 18:48:41
	(b) (4)	

US3552053

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 18:49:20

US3552053

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered '01 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 18:49:20

US3552053

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered '11:40'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 18:49:20



**US3552053**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:08:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered '01 Mar 2021 11:40'	System	01 Mar 2021 18:49:20

US3552053

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:50:55
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Mar 2021 18:49:24

US3552053

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:02
User entered 'I'	System	01 Mar 2021 18:49:24

US3552053

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:58:25
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Apr 2021 15:43:18

US3552053

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:58:25
User entered '12 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Apr 2021 15:43:18

US3552053

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:58:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Apr 2021 15:43:18

US3552053

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:58:25
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Apr 2021 15:43:18

US3552053

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:58:25
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	12 Apr 2021 15:43:24



**US3552053**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:08:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:43:24

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:52:53

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '11 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:52:53

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:15

[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 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:52:53

**US3552053**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:08:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 16:52:53

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:15

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '11 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:53:08

**US3552053**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:08:15**

[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 19:53:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:22:23
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:55:25

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:15

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:53:08



US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:22:23
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:55:25

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:15

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '11 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:53:08

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Dublin (b) (4)	11 Jan 2021 16:53:08

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 12:07:26
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Dublin (b) (4)	11 Jan 2021 16:53:08
	(b) (4)	

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 12:07:26
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Doublin (b) (4)	11 Jan 2021 16:53:08
	(b) (4)	

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:53:08

**US3552053**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:08:15**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User entered empty.	System	11 Jan 2021 16:53:08

**US3552053**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:08:15**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User entered empty.	System	11 Jan 2021 16:53:08



US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:53:19

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '11 Jan 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	11 Jan 2021 16:53:19

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '09:55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:53:19

**US3552053**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:08:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User entered '11 Jan 2021 09:55'	System	11 Jan 2021 16:53:19

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:53:31

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '11 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:53:31

US3552053

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10:00'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 16:53:31

**US3552053**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:08:15**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:39
User entered '11 Jan 2021 10:00'	System	11 Jan 2021 16:53:31



US3552053

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:08:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:26:29
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:13:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:45:46
User entered 'Yes (Y)'	Heather Douds (b) (4)	01 Sep 2020 20:58:59

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental pain and sensation disorders, PT: Toothache, LLT: Tooth ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 21:00:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 21:00:38
Data point term sent to Coder	System	01 Sep 2020 21:00:06
User entered 'Tooth ache'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	17 Sep 2020 00:00:25
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	14 Sep 2020 18:07:51
User entered '28 Aug 2020'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User entered empty.	System	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)' reason for change: Data Entry Error	Joan Siegner (b) (4)	15 Sep 2020 20:17:59
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '04 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	15 Sep 2020 20:17:59
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User entered empty.	System	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Heather Douds (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Heather Douds (b) (4)	01 Sep 2020 21:00:04
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Heather Douds (b) (4)	01 Sep 2020 21:00:04
	(b) (4)	

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

US3552053

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04



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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 21:00:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 21:00:12
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:12
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 21:00:04
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'l'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	15 Sep 2020 20:17:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04



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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Heather Douds (b) (4) (b) (4)	01 Sep 2020 21:00:04

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User entered '0'	System	01 Sep 2020 21:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10
User entered 'I'	System	01 Sep 2020 21:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:10

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Folder: Adverse Events

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:54
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:46:23
User entered	System	18 Sep 2020 17:46:17
'USA-US089-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	18 Sep 2020 17:46:17

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:14:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:14:29
Data point term sent to Coder	System	14 Oct 2020 15:13:37
User closed query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) INTRACTABLE VOMITING 2) NAUSEA etc.'	System	14 Oct 2020 15:13:17
(Site from System).		
Query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) INTRACTABLE VOMITING 2) NAUSEA etc.'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:13:17
answered with 'updated' (Site from System).		
User entered 'INTRACTABLE VOMITING' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:12:56
User opened query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) INTRACTABLE VOMITING 2) NAUSEA etc.'	Coder Import (b) (4) (b) (4)	14 Oct 2020 06:00:20
(Site from System).		
Data point term sent to Coder	System	13 Oct 2020 16:32:39
Coding entries removed.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 16:31:50
User entered 'INTRACTABLE VOMITING with nausea' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	13 Oct 2020 16:31:50
User closed query 'Please consider updating to Intractable vomiting with nausea per PCP discharge summary. ' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 15:25:49

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).</td <td>(b) (4), (b) (6)</td> <td>12 Oct 2020 10:26:27</td>	(b) (4), (b) (6)	12 Oct 2020 10:26:27
User coded data point as SOC: Gastrointestinal disorders, HLGTT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 21:30:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 21:30:30
Data point term sent to Coder	System	09 Oct 2020 16:02:54
User closed query 'For coding purposes, please split INTRACTABLE VOMITING WITH NAUSEA into separate entries' (Site from System).	System	09 Oct 2020 16:02:41
Query 'For coding purposes, please split INTRACTABLE VOMITING WITH NAUSEA into separate entries' answered with 'updated per query request' (Site from System).	Cassandra Zehenny (b) (4)	09 Oct 2020 16:02:41
User entered 'INTRACTABLE VOMITING' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	09 Oct 2020 16:02:02
User opened query 'For coding purposes, please split INTRACTABLE VOMITING WITH NAUSEA into separate entries' (Site from System).	Coder Import (b) (4)	08 Oct 2020 11:39:18
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'done' (Site from DM).</td <td>Heather Douds (b) (4)</td> <td>06 Oct 2020 16:56:17</td>	Heather Douds (b) (4)	06 Oct 2020 16:56:17
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).</td <td>(b) (4), (b) (6)</td> <td>06 Oct 2020 10:01:09</td>	(b) (4), (b) (6)	06 Oct 2020 10:01:09



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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Query 'Please consider updating to Intractable vomiting with nausea per PCP discharge summary. ' answered with 'done' (Site from CRA). Data point term sent to Coder Coding entries removed.	Joan Siegner (b) (4) System Joan Siegner (b) (4)	05 Oct 2020 16:41:24 05 Oct 2020 16:41:14 05 Oct 2020 16:40:37
User entered 'INTRACTABLE vomiting with nausea' reason for change: Data Entry Error	Joan Siegner (b) (4)	05 Oct 2020 16:40:37
User opened query 'Please consider updating to Intractable vomiting with nausea per PCP discharge summary. ' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 14:22:00
User closed query 'PV Query: The event term reported is "Nausea and dehydration"; however, it does not appear that the subject was diagnosed with dehydration during hospital admission. Please assess and consider whether the event term should be updated to "Intractable nausea" per the discharge diagnosis. Any additional event terms must be captured on separate AE log lines/CRFs.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 18:51:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 18:21:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 18:21:42
Data point term sent to Coder	System	29 Sep 2020 16:50:31
Query 'PV Query: The event term reported is "Nausea and dehydration"; however, it does not appear that the subject was diagnosed with dehydration during hospital admission. Please assess and consider whether the event term should be updated to "Intractable nausea" per the discharge diagnosis. Any additional event terms must be captured on separate AE log lines/CRFs.' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	29 Sep 2020 16:49:46
User entered 'intractable nausea' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 16:49:38

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The event term reported is "Nausea and dehydration"; however, it does not appear that the subject was diagnosed with dehydration during hospital admission. Please assess and consider whether the event term should be updated to "Intractable nausea" per the discharge diagnosis. Any additional event terms must be captured on separate AE log lines/CRFs.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:05:33
Data point term sent to Coder	System	18 Sep 2020 16:23:55
Coding entries removed.	Heather Douds (b) (4)	18 Sep 2020 16:23:39
User entered 'NAUSEA & dehydration' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	18 Sep 2020 16:23:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 13:39:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
	Coder Import (b) (4)	18 Sep 2020 13:39:47
Data point term sent to Coder	System	18 Sep 2020 13:38:32
User entered 'NAUSEA' reason for change: Data Entry Error	Heather Douds (b) (4)	18 Sep 2020 13:37:39
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 13:20:03
User entered 'Headache/Nausea'	Heather Douds (b) (4)	18 Sep 2020 13:19:12
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:18:48
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:18:50
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	13 Oct 2020 18:18:52
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:18:53
User closed query 'PV Query: Please confirm the start date of the event. Symptoms were reported starting on 15 Sep 2020, but onset date reported as 16 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 18:51:27
Query 'PV Query: Please confirm the start date of the event. Symptoms were reported starting on 15 Sep 2020, but onset date reported as 16 Sep 2020.' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	29 Sep 2020 16:51:12
User entered '15 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 16:50:56
User opened query 'PV Query: Please confirm the start date of the event. Symptoms were reported starting on 15 Sep 2020, but onset date reported as 16 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:07:04
User entered '16 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	18 Sep 2020 13:38:57
User entered '15 Sep 2020'	Heather Douds (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:18:55
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:57:52
User entered '12:00' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	29 Sep 2020 16:57:52
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:50:56
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 13:38:57
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 13:19:12
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	29 Sep 2020 16:57:52
User entered empty.	System	18 Sep 2020 13:19:12



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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:18:56
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	26 Sep 2020 17:36:14
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	13 Oct 2020 18:18:59
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Sep 2020 17:37:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Sep 2020 17:37:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Sep 2020 17:36:14
User entered '21 Sep 2020' reason for change: New Information	Heather Douds (b) (4)	26 Sep 2020 17:36:14
User entered empty.	Heather Douds (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 12:27:33
Query 'Data is required. Please provide.' answered with 'data is unknown and is not required' (Site from System).	Joan Siegner (b) (4)	29 Sep 2020 16:58:17
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:50:56
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 13:19:12

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:02
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:37:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	13 Oct 2020 18:19:04
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Sep 2020 13:19:57
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Sep 2020 13:19:12
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:07
User entered '0'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:08
User entered '0'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:10
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		21 Sep 2020 13:14:00
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		21 Sep 2020 13:14:00
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		18 Sep 2020 13:19:57
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		18 Sep 2020 13:19:57
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 13:19:57
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	18 Sep 2020 13:19:57
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	18 Sep 2020 13:19:12
User entered '0'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:12
User entered '17 Sep 2020'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

US3552053

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:13
User closed query 'Per narrative below, discharge date is 18Sep2020, Please reconcile' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 15:58:50
Query 'Per narrative below, discharge date is 18Sep2020, Please reconcile' answered with 'corrected' (Site from CRA).	Joan Siegner (b) (4)	25 Sep 2020 11:12:31
User entered '18 Sep 2020' reason for change: New Information	Joan Siegner (b) (4)	25 Sep 2020 11:12:21
User opened query 'Per narrative below, discharge date is 18Sep2020, Please reconcile' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 17:13:05
Query 'Per submitted narrative below, discharge date is 19Sep2020, Please reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 17:12:49
User opened query 'Per submitted narrative below, discharge date is 19Sep2020, Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 17:12:37
User entered '17 Sep 2020' reason for change: New Information	Heather Douds (b) (4) (b) (4)	21 Sep 2020 13:14:00
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:16
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:18
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:20
User entered '0'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:32
User entered '0'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:34
User entered '0'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12



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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:36
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:42:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 13:42:38
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:42:38
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:19:12
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:19:37
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:42:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 13:42:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:42:38
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:19:12
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:22:33
DataPoint Un-verified.	(b) (4), (b) (6)	13 Oct 2020 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 18:19:42
User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 14 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:11:31
Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 14 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	29 Sep 2020 16:58:45
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 16:58:38
User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 14 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:05:58
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:42:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 13:42:38
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:42:38
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:19:12
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:22:36
User entered '0'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:22:38
User entered 'l'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:22:39
User entered '0'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:22:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	26 Sep 2020 17:37:24
User entered 'Unknown (UNKNOWN)'	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:22:43
User entered empty.	Heather Douds (b) (4) (b) (4)	18 Sep 2020 13:19:12



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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	13 Oct 2020 18:22:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/16 TO REPORT MODERATE HEADACHE AND MILD NAUSEA WHICH STARTED ON 9/15; STATED HEADACHE HAD IMPROVED (MILD) BUT NAUSEA WAS SEVERE, ONGOING AND WORSENING. STATED SHE HAD NOT BEEN ABLE TO DRINK MUCH AND WASN'T ABLE TO KEEP FOOD DOWN. PER SUBJECT, ON 9/15, SHE DRANK "TWENTY TWO OUNCES" OF FLUID, NO FOOD, AND HAD "ONLY A FEW SIPS OF FLUIDS" ON 9/16 AT TIME OF CALL. SITE RECOMMENDED SHE VISIT URGENT CARE, WHICH SHE DID THE EVENING OF 9/16, RECEIVED FLUIDS AND A DOSE OF ZOFRAN. SITE CALLED TO FOLLOW UP THE MORNING OF 9/17, SUBJECT REPORTED FEELING MUCH BETTER AND THAT BOTH HEADACHE AND NAUSEA HAD IMPROVED TO MILD, AND THAT SHE HAD BEEN PROVIDED A PRESCRIPTION FOR ZOFRAN THAT SHE HAD NOT YET FILLED. SITE RECEIVED A CALL THE EVENING OF 9/17 FROM SUBJECT'S HUSBAND STATING THE SUBJECT'S SYMPTOMS HAD WORSENERD AGAIN, SUBJECT WAS UNABLE TO KEEP FLUIDS DOWN AND THAT THEY WANTED TO GO TO THE EMERGENCY ROOM; THEY HAD FILLED THE ZOFRAN AND TAKEN A DOSE "A FEW MINUTES" BEFORE THE CALL WITHOUT IMPROVEMENT. SITE ADVISED THEM TO GO IF THEY FELT THEY NEEDED TO; SUBJECT'S HUSBAND MENTIONED DURING THE PHONE CALL THAT SUBJECT HAS A HISTORY OF HEADACHES WITH SEVERE NAUSEA THAT HAS LED TO HOSPITAL ADMISSIONS IN THE PAST. THE INFORMATION REGARDING HER HEADACHES HAD NOT BEEN PROVIDED TO SITE AT SCREENING PRIOR TO ENROLLMENT. SUBJECT WAS ADMITTED OVERNIGHT ON 9/17, SUBJECT WAS DISCHARGED ON 18SEP2020.' reason for change: New Information	Joan Siegner (b) (4)	05 Oct 2020 16:41:04

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/16 TO REPORT MODERATE HEADACHE AND MILD NAUSEA WHICH STARTED ON 9/15; STATED HEADACHE HAD IMPROVED (MILD) BUT NAUSEA WAS SEVERE, ONGOING AND WORSENING. STATED SHE HAD NOT BEEN ABLE TO DRINK MUCH AND WASN'T ABLE TO KEEP FOOD DOWN. PER SUBJECT, ON 9/15, SHE DRANK "TWENTY TWO OUNCES" OF FLUID, NO FOOD, AND HAD "ONLY A FEW SIPS OF FLUIDS" ON 9/16 AT TIME OF CALL. SITE RECOMMENDED SHE VISIT URGENT CARE, WHICH SHE DID THE EVENING OF 9/16, RECEIVED FLUIDS AND A DOSE OF ZOFRAN. SITE CALLED TO FOLLOW UP THE MORNING OF 9/17, SUBJECT REPORTED FEELING MUCH BETTER AND THAT BOTH HEADACHE AND NAUSEA HAD IMPROVED TO MILD, AND THAT SHE HAD BEEN PROVIDED A PRESCRIPTION FOR ZOFRAN THAT SHE HAD NOT YET FILLED. SITE RECEIVED A CALL THE EVENING OF 9/17 FROM SUBJECT'S HUSBAND STATING THE SUBJECT'S SYMPTOMS HAD WORSENERD AGAIN, SUBJECT WAS UNABLE TO KEEP FLUIDS DOWN AND THAT THEY WANTED TO GO TO THE EMERGENCY ROOM; THEY HAD FILLED THE ZOFRAN AND TAKEN A DOSE "A FEW MINUTES" BEFORE THE CALL WITHOUT IMPROVEMENT. SITE ADVISED THEM TO GO IF THEY FELT THEY NEEDED TO; SUBJECT'S HUSBAND MENTIONED DURING THE PHONE CALL THAT SUBJECT HAS A HISTORY OF HEADACHES WITH SEVERE NAUSEA THAT HAS LED TO HOSPITAL ADMISSIONS IN THE PAST. THE INFORMATION REGARDING HER HEADACHES HAD NOT BEEN PROVIDED TO SITE AT SCREENING PRIOR TO ENROLLMENT. SUBJECT WAS ADMITTED OVERNIGHT ON 9/17, SUBJECT WAS DISCHARGED ON 19SEP2020.' reason for change: New Information	Joan Siegner (b) (4)	05 Oct 2020 16:40:37

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Please capture labs taken on 09/18/20 and 09/17/20 under Unscheduled labs eCRF. ' canceled (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 15:01:13
User opened query 'Please capture labs taken on 09/18/20 and 09/17/20 under Unscheduled labs eCRF. ' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 14:46:58
User closed query 'PV Query: Please confirm that the subject did not take any additional doses of Keflex (cephalexin) beyond 04 Sep 2020 and amend the concomitant medications eCRF, if needed.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:11:49
User closed query 'PV Query: The subject reported that she took medications to treat the headache. Please record all over the counter and prescription medications taken by the subject to treat the headache on the concomitant medications eCRF, including dose and frequency.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:11:47
User closed query 'PV Query: Please inquire and report as to whether the subject has had any medical testing or investigation into the cause of her previous headaches with severe nausea leading to past hospitalizations (i.e. migraines, linked to IBS, etc.).' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:11:44
User closed query 'PV Query: Please provide results of covid testing done subsequent to the day 29 test (ie. while hospitalized).' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:11:41
User closed query 'PV Query: Per case narrative, the subject had a history of headaches with severe nausea. Please add these conditions to medical history.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:11:36
Query 'PV Query: The subject reported that she took medications to treat the headache. Please record all over the counter and prescription medications taken by the subject to treat the headache on the concomitant medications eCRF, including dose and frequency.' answered with 'subject did not take medication for headache' (Site from Safety).	Joan Siegner (b) (4)	29 Sep 2020 17:09:55
Query 'PV Query: Please provide results of covid testing done subsequent to the day 29 test (ie. while hospitalized).' answered with 'no covid testing done while hospitalized' (Site from Safety).	Joan Siegner (b) (4)	29 Sep 2020 17:08:41

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please inquire and report as to whether the subject has had any medical testing or investigation into the cause of her previous headaches with severe nausea leading to past hospitalizations (i.e. migraines, linked to IBS, etc.).' answered with 'no investigation done in the past' (Site from Safety).	Joan Siegner (b) (4)	29 Sep 2020 17:07:59
Query 'PV Query: Per case narrative, the subject had a history of headaches with severe nausea. Please add these conditions to medical history.' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	29 Sep 2020 17:07:28
Query 'PV Query: Please confirm that the subject did not take any additional doses of Keflex (cephalexin) beyond 04 Sep 2020 and amend the concomitant medications eCRF, if needed.' answered with 'keflex stop date is confirmed 04SEP2020' (Site from Safety).	Joan Siegner (b) (4)	29 Sep 2020 16:47:48
User opened query 'PV Query: Please confirm that the subject did not take any additional doses of Keflex (cephalexin) beyond 04 Sep 2020 and amend the concomitant medications eCRF, if needed.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:07:49
User opened query 'PV Query: The subject reported that she took medications to treat the headache. Please record all over the counter and prescription medications taken by the subject to treat the headache on the concomitant medications eCRF, including dose and frequency.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:07:40
User opened query 'PV Query: Please inquire and report as to whether the subject has had any medical testing or investigation into the cause of her previous headaches with severe nausea leading to past hospitalizations (i.e. migraines, linked to IBS, etc.).' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:07:30
User opened query 'PV Query: Please provide results of covid testing done subsequent to the day 29 test (ie. while hospitalized).' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:07:19
User opened query 'PV Query: Per case narrative, the subject had a history of headaches with severe nausea. Please add these conditions to medical history.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:06:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/16 TO REPORT MODERATE HEADACHE AND MILD NAUSEA WHICH STARTED ON 9/15; STATED HEADACHE HAD IMPROVED (MILD) BUT NAUSEA WAS SEVERE, ONGOING AND WORSENING. STATED SHE HAD NOT BEEN ABLE TO DRINK MUCH AND WASN'T ABLE TO KEEP FOOD DOWN. PER SUBJECT, ON 9/15, SHE DRANK "TWENTY TWO OUNCES" OF FLUID, NO FOOD, AND HAD "ONLY A FEW SIPS OF FLUIDS" ON 9/16 AT TIME OF CALL. SITE RECOMMENDED SHE VISIT URGENT CARE, WHICH SHE DID THE EVENING OF 9/16, RECEIVED FLUIDS AND A DOSE OF ZOFRAN. SITE CALLED TO FOLLOW UP THE MORNING OF 9/17, SUBJECT REPORTED FEELING MUCH BETTER AND THAT BOTH HEADACHE AND NAUSEA HAD IMPROVED TO MILD, AND THAT SHE HAD BEEN PROVIDED A PRESCRIPTION FOR ZOFRAN THAT SHE HAD NOT YET FILLED. SITE RECEIVED A CALL THE EVENING OF 9/17 FROM SUBJECT'S HUSBAND STATING THE SUBJECT'S SYMPTOMS HAD WORSENERD AGAIN, SUBJECT WAS UNABLE TO KEEP FLUIDS DOWN AND THAT THEY WANTED TO GO TO THE EMERGENCY ROOM; THEY HAD FILLED THE ZOFRAN AND TAKEN A DOSE "A FEW MINUTES" BEFORE THE CALL WITHOUT IMPROVEMENT. SITE ADVISED THEM TO GO IF THEY FELT THEY NEEDED TO; SUBJECT'S HUSBAND MENTIONED DURING THE PHONE CALL THAT SUBJECT HAS A HISTORY OF HEADACHES WITH SEVERE NAUSEA THAT HAS LED TO HOSPITAL ADMISSIONS IN THE PAST. THE INFORMATION REGARDING HER HEADACHES HAD NOT BEEN PROVIDED TO SITE AT SCREENING PRIOR TO ENROLLMENT. SUBJECT WAS ADMITTED OVERNIGHT ON 9/17, SUBJECT WAS DISCHARGED ON 18SEP2020.' reason for change: New Information	Joan Siegner (b) (4)	22 Sep 2020 12:56:17

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/16 TO REPORT MODERATE HEADACHE AND MILD NAUSEA WHICH STARTED ON 9/15; STATED HEADACHE HAD IMPROVED (MILD) BUT NAUSEA WAS SEVERE, ONGOING AND WORSENING. STATED SHE HAD NOT BEEN ABLE TO DRINK MUCH AND WASN'T ABLE TO KEEP FOOD DOWN. PER SUBJECT, ON 9/15, SHE DRANK "TWENTY TWO OUNCES" OF FLUID, NO FOOD, AND HAD "ONLY A FEW SIPS OF FLUIDS" ON 9/16 AT TIME OF CALL. SITE RECOMMENDED SHE VISIT URGENT CARE, WHICH SHE DID THE EVENING OF 9/16, RECEIVED FLUIDS AND A DOSE OF ZOFRAN. SITE CALLED TO FOLLOW UP THE MORNING OF 9/17, SUBJECT REPORTED FEELING MUCH BETTER AND THAT BOTH HEADACHE AND NAUSEA HAD IMPROVED TO MILD, AND THAT SHE HAD BEEN PROVIDED A PRESCRIPTION FOR ZOFRAN THAT SHE HAD NOT YET FILLED. SITE RECEIVED A CALL THE EVENING OF 9/17 FROM SUBJECT'S HUSBAND STATING THE SUBJECT'S SYMPTOMS HAD WORSENERD AGAIN, SUBJECT WAS UNABLE TO KEEP FLUIDS DOWN AND THAT THEY WANTED TO GO TO THE EMERGENCY ROOM; THEY HAD FILLED THE ZOFRAN AND TAKEN A DOSE "A FEW MINUTES" BEFORE THE CALL WITHOUT IMPROVEMENT. SITE ADVISED THEM TO GO IF THEY FELT THEY NEEDED TO; SUBJECT'S HUSBAND MENTIONED DURING THE PHONE CALL THAT SUBJECT HAS A HISTORY OF HEADACHES WITH SEVERE NAUSEA THAT HAS LED TO HOSPITAL ADMISSIONS IN THE PAST. THE INFORMATION REGARDING HER HEADACHES HAD NOT BEEN PROVIDED TO SITE AT SCREENING PRIOR TO ENROLLMENT. SUBJECT WAS ADMITTED OVERNIGHT ON 9/17, WILL REQUEST RECORDS AND UPDATE ADVERSE EVENT	Heather Douds (b) (4)	21 Sep 2020 13:14:38

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:15

[Narrative](#)

Audit	User	Time (GMT)
ONCE MORE INFORMATION IS AVAILABLE. Subject was discharged on 18SEP2020.' reason for change: New Information		
User entered 'Subject contacted site on 9/16 to report moderate headache and mild nausea which started on 9/15; stated headache had improved (mild) but nausea was severe, ongoing and worsening. Stated she had not been able to drink much and wasn't able to keep food down. Per subject, on 9/15, she drank "twenty two ounces" of fluid, no food, and had "only a few sips of fluids" on 9/16 at time of call. Site recommended she visit urgent care, which she did the evening of 9/16, received fluids and a dose of Zofran. Site called to follow up the morning of 9/17, subject reported feeling much better and that both headache and nausea had improved to mild, and that she had been provided a prescription for Zofran that she had not yet filled. Site received a call the evening of 9/17 from subject's husband stating the subject's symptoms had worsened again, subject was unable to keep fluids down and that they wanted to go to the emergency room; they had filled the Zofran and taken a dose "a few minutes" before the call without improvement. Site advised them to go if they felt they needed to; subject's husband mentioned during the phone call that subject has a history of headaches with severe nausea that has led to hospital admissions in the past. The information regarding her headaches had not been provided to site at screening prior to enrollment. Subject was admitted overnight on 9/17, will request records and update adverse event once more information is available.'	Heather Douds (b) (4)	18 Sep 2020 13:19:12



**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Sep 2020 13:19:12

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 13:19:12

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 13:19:12

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:08:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Per source, subject reported Headache on 15Sep. Please consider adding event to AE eCRF. Thank you' (Site from CRA).	(b) (4)	
Query 'Per source, subject reported Headache on 15Sep. Please consider adding event to AE eCRF. Thank you' answered with 'within 7 day diary period, AR, not AE. thank you!' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 15:46:19
User opened query 'Per source, subject reported Headache on 15Sep. Please consider adding event to AE eCRF. Thank you' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 19:19:27
Query 'Per source, subject reported AE on 15Sep. Please consider adding event to AE eCRF. Thank you! ' canceled (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 16:00:37
User opened query 'Per source, subject reported AE on 15Sep. Please consider adding event to AE eCRF. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 16:00:21
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:59
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.	(b) (4), (b) (6)	28 Oct 2020 15:59:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 14:06:39
Data point term sent to Coder	(b) (4)	
User entered 'diarrhea'	Coder Import (b) (4)	21 Sep 2020 14:06:39
	System	21 Sep 2020 14:06:14
	Stanley Doublin (b) (4)	21 Sep 2020 14:05:41
	(b) (4)	

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	21 Sep 2020 14:05:41



US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '19 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User entered empty.	System	21 Sep 2020 14:05:41

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '19 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User entered empty.	System	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41



US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41



US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Stanley Doublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Related (RELATED)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Not Related (NOT RELATED)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:44:44
User closed query 'Please change to not applicable, as event started after last dose ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:44:42
Query 'Please change to not applicable, as event started after last dose ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	23 Nov 2020 15:31:05
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	23 Nov 2020 15:31:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4)	23 Nov 2020 15:31:00
User opened query 'Please change to not applicable, as event started after last dose ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 16:34:53
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'None (NONE)'	Stanley Doublin (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'l'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41



US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 14:05:41

US3552053

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:15

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User entered '0'	System	21 Sep 2020 14:05:41

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11
User entered '0'	System	21 Sep 2020 14:05:41

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:26:11

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 21:25:14
User entered 'USA-US089-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	12 Oct 2020 21:25:08



US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:50
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:05:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:05:25
Data point term sent to Coder	System	09 Oct 2020 16:04:59
User entered 'Nausea'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '15 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Oct 2020 16:05:15
User entered '12:00' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:05:15
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Oct 2020 16:04:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:08:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	09 Oct 2020 16:05:15
User entered empty.	System	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31



US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '21 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 12:00:33
Query 'Data is required. Please provide.' answered with 'data unknown' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:05:30
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Oct 2020 16:04:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:08:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Grade 4 (Grade 4)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'I'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31



US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '17 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '18 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User closed query 'PV Query: Please consider updating the action taken with the study drug in response to the event of nausea, from none to not applicable as the subject had already taken both the scheduled doses of the study drug prior to the event onset.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 16:37:09
Query 'PV Query: Please consider updating the action taken with the study drug in response to the event of nausea, from none to not applicable as the subject had already taken both the scheduled doses of the study drug prior to the event onset.' answered with 'Updated per query request' (Site from Safety).	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 13:57:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 13:56:53
User opened query 'PV Query: Please consider updating the action taken with the study drug in response to the event of nausea, from none to not applicable as the subject had already taken both the scheduled doses of the study drug prior to the event onset.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 17:24:17
User entered 'None (NONE)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Oct 2020 16:06:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Oct 2020 16:04:31
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '1' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	09 Oct 2020 16:06:26
User entered '0'	Cassandra Zehenny (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:14
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	28 Oct 2020 15:59:14



US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/16 TO REPORT MODERATE HEADACHE AND MILD NAUSEA WHICH STARTED ON 9/15; STATED HEADACHE HAD IMPROVED (MILD) BUT NAUSEA WAS SEVERE, ONGOING AND WORSENING. STATED SHE HAD NOT BEEN ABLE TO DRINK MUCH AND WASN'T ABLE TO KEEP FOOD DOWN. PER SUBJECT, ON 9/15, SHE DRANK "TWENTY TWO OUNCES" OF FLUID, NO FOOD, AND HAD "ONLY A FEW SIPS OF FLUIDS" ON 9/16 AT TIME OF CALL. SITE RECOMMENDED SHE VISIT URGENT CARE, WHICH SHE DID THE EVENING OF 9/16, RECEIVED FLUIDS AND A DOSE OF ZOFRAN. SITE CALLED TO FOLLOW UP THE MORNING OF 9/17, SUBJECT REPORTED FEELING MUCH BETTER AND THAT BOTH HEADACHE AND NAUSEA HAD IMPROVED TO MILD, AND THAT SHE HAD BEEN PROVIDED A PRESCRIPTION FOR ZOFRAN THAT SHE HAD NOT YET FILLED. SITE RECEIVED A CALL THE EVENING OF 9/17 FROM SUBJECT'S HUSBAND STATING THE SUBJECT'S SYMPTOMS HAD WORSENERD AGAIN, SUBJECT WAS UNABLE TO KEEP FLUIDS DOWN AND THAT THEY WANTED TO GO TO THE EMERGENCY ROOM; THEY HAD FILLED THE ZOFRAN AND TAKEN A DOSE "A FEW MINUTES" BEFORE THE CALL WITHOUT IMPROVEMENT. SITE ADVISED THEM TO GO IF THEY FELT THEY NEEDED TO; SUBJECT'S HUSBAND MENTIONED DURING THE PHONE CALL THAT SUBJECT HAS A HISTORY OF HEADACHES WITH SEVERE NAUSEA THAT HAS LED TO HOSPITAL ADMISSIONS IN THE PAST. THE INFORMATION REGARDING HER HEADACHES HAD NOT BEEN PROVIDED TO SITE AT SCREENING PRIOR TO ENROLLMENT. SUBJECT WAS ADMITTED OVERNIGHT ON 9/17, SUBJECT WAS DISCHARGED ON 18SEP2020.'	Cassandra Zehenny (b) (4)	(b) (4) 09 Oct 2020 16:04:31

US3552053

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:15

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 16:04:31

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 16:04:31

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 16:04:31

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:08:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07

Adverse event

PRODUCTION RELEASE (v12.003  
EAB) (1725)

US3552053

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	30 Nov 2020 19:22:55
Coding entries removed.	Cassandra Zehenny (b) (4)	30 Nov 2020 19:22:54
User entered 'WORSENING ARRHYTHMIA [pre-ventricular contractions]' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Nov 2020 19:22:54
User opened query 'Per DM CLR: Please review and specify the type of Arrhythmia (e.g., Sinus Tachycardia, Atrial Fibrillation, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	28 Nov 2020 05:10:31
' (Site from DM).		
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:38:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:38:56
Data point term sent to Coder	System	23 Nov 2020 14:38:02
Coding entries removed.	Heather Douds (b) (4)	23 Nov 2020 14:38:00
User entered 'worsening ARRHYTHMIA' reason for change: New Information	Heather Douds (b) (4)	23 Nov 2020 14:38:00
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 16:57:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 16:57:46
Data point term sent to Coder	System	13 Nov 2020 16:57:05
User entered 'Arrhythmia'	Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

US3552053

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33



US3552053

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

US3552053

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

US3552053

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10 Nov 2020'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

US3552053

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

US3552053

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User entered empty.	System	13 Nov 2020 16:56:33

US3552053

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	16 Dec 2020 15:41:21
User entered 'Yes (Y)'	(b) (4)	
	Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '14 Dec 2020' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	16 Dec 2020 15:41:21
User entered empty.	(b) (4)	
	Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33



**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:08:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User entered empty.	System	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33
	(b) (4)	



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Generated On: 10 Jun 2021 08:08:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'l'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	
User entered 'Unknown (UNKNOWN)'	Cassandra Zehenny (b) (4)	16 Dec 2020 15:41:21
	(b) (4)	
	Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	13 Nov 2020 16:56:33

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:08:15**

**Serious Adverse Event Derived (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User entered '0'	System	13 Nov 2020 16:56:33

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07
User entered '1'	System	13 Nov 2020 16:56:33



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:21:07

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 16:56:59
Data point term sent to Coder	(b) (4)	
Coding entries removed.	Coder Import (b) (4)	10 Dec 2020 16:56:59
	System	10 Dec 2020 16:56:10
	Cassandra Zehenny (b) (4)	10 Dec 2020 16:55:42
	(b) (4)	
User entered 'MITRAL VALVE REGURGITATION' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 16:55:42
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 12:16:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	24 Nov 2020 12:16:10
User entered 'nitrite valve regurgitation'	System	23 Nov 2020 19:41:40
	Stanley Dublin (b) (4)	23 Nov 2020 19:40:58
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Form: Adverse Events (7)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '19 Nov 2020'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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**Folder: Adverse Events**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:40:58



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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	23 Nov 2020 19:41:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 19:41:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:41:07
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:40:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:40:58

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

Form: Adverse Events (7)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58



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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

Form: Adverse Events (7)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58



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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

Form: Adverse Events (7)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	23 Nov 2020 19:41:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 19:41:25
User entered 'None (NONE)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:41:25
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:40:58
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'I'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Form: Adverse Events (7)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

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Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:15

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58



US3552053

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 19:40:58

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:08:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 19:40:58

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:08:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Nov 2020 19:40:58

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:08:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 08:52:58
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:18:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:18:51
Data point term sent to Coder	System	15 Dec 2020 22:59:41
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 22:59:35
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 22:59:30
User entered 'MIGRAINES/headache exacerbation' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 22:59:30
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 06:27:06
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:15:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	23 Nov 2020 20:15:18
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 19:42:41
User entered 'migraines'	Stanley Doublin (b) (4)	23 Nov 2020 19:42:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '19 Nov 2020'	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User entered empty.	System	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)' reason for change: New Information	(b) (4) Cassandra Zehenny (b) (4)	10 Dec 2020 16:55:29
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10 Dec 2020' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 16:55:29
User entered empty.	(b) (4)	
	Stanley Dublin (b) (4)	23 Nov 2020 19:42:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:08:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User entered empty.	System	23 Nov 2020 19:42:14



US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 11:48:39
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	14 Jan 2021 22:52:52
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Per Query Resolution	(b) (4)	14 Jan 2021 22:52:46
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:19:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Doublin (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Stanley Doublin (b) (4)	23 Nov 2020 19:42:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'None (NONE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Cassandra Zehenny (b) (4)	10 Dec 2020 16:55:29
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stanley Doublin (b) (4)	23 Nov 2020 19:42:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 19:42:14

US3552053

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:08:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered empty.	(b) (4) Stanley Dublin (b) (4)	23 Nov 2020 19:42:14

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:08:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User entered '0'	System	23 Nov 2020 19:42:14

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:08:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04
User entered 'I'	System	23 Nov 2020 19:42:14

**US3552053**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:08:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:20:04



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:08:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:26:29
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:13:31
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:39:44
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'medical history #21. has not received within 30 days of start of study' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	23 Mar 2021 14:56:28
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:16:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:08:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, 3, 4 and 5 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 12:28:29
Query 'Per DM CLR: Per Diary Dose 2 Day 2, 3, 4 and 5 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' ' answered with 'con med #5-6, entered as reported by subject when asked about medication taken' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	09 Feb 2021 16:08:47
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, 3, 4 and 5 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 11:23:02
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:51:43
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:51:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:54:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:54:10
Data point term sent to Coder	System	18 Aug 2020 15:53:44
User entered 'melatonin'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'insomnia'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '5' reason for change: Data Entry Error	Heather Douds (b) (4)	18 Aug 2020 19:26:17
User entered '50'	(b) (4) Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'mg (mg)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49



US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'as needed (PRN)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 11:26:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'data is correct' (Site from System).	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:52:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:52:49
User entered 'un UNK 2015'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '0'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 15:53:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 15:53:09
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:09
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 15:52:49
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:52:49

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:52:49

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:52:49

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:52:49

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:56:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 15:56:07
Data point term sent to Coder	System	18 Aug 2020 15:54:46
User entered 'benadryl'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'insomnia'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '25'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'mg (mg)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:08:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'as needed (PRN)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:08:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 11:26:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'data is correct' (Site from System).	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:54:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:53:57
User entered 'un UNK 2015'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '0'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:53:57

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:53:57

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:53:57

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:53:57

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE ACETATE, PRODUCTSYNONYM: PRED FORTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:54:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:54:35
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	23 Oct 2020 14:31:43 23 Oct 2020 14:31:39
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE ACETATE, PRODUCTSYNONYM: PRED FORTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:34:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:34:46
Data point term sent to Coder User entered 'pred forte 1%'	System Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:59:58 18 Aug 2020 15:59:07

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User closed query 'Per DM CLR: Please review and update the CM indication to include the specific location of the CHRONIC UVEITIS (i.e.: Right, Left or Bilateral Eyes). Review and update the CM page and ensure reconciliation with the AE/MH pages so there is a match as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:17:17
Query 'Per DM CLR: Please review and update the CM indication to include the specific location of the CHRONIC UVEITIS (i.e.: Right, Left or Bilateral Eyes). Review and update the CM page and ensure reconciliation with the AE/MH pages so there is a match as appropriate. ' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	23 Oct 2020 14:31:44
User entered 'CHRONIC Right eye UVEITIS' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	23 Oct 2020 14:31:39
User opened query 'Per DM CLR: Please review and update the CM indication to include the specific location of the CHRONIC UVEITIS (i.e.: Right, Left or Bilateral Eyes). Review and update the CM page and ensure reconciliation with the AE/MH pages so there is a match as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 03:52:11
User entered 'chronic uveitis'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'l'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Other (OTHER)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:08:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'drop'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'as needed (PRN)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:08:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Topical (TOPICAL)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:08:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 11:27:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'data is correct' (Site from System).	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:59:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 15:59:07
User entered 'un UNK 1989'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '0'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	18 Aug 2020 15:59:07

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:59:07

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:59:07

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 15:59:07



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFLEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 05:03:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 05:03:37
Data point term sent to Coder	System	31 Aug 2020 17:23:31
User entered 'keflex'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 17:22:40

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Stanley Doublin (b) (4)	31 Aug 2020 17:22:40
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:16:41
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'Please see AE for tooth ache' (Site from DM).	Heather Douds (b) (4) (b) (4)	07 Oct 2020 17:24:59
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:45:54
User entered 'toothache'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 17:22:40

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '500'	Stanley Doublin (b) (4)	31 Aug 2020 17:22:40
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 17:22:40

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4)	31 Aug 2020 17:22:40
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'three times daily (TID)'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 17:22:40

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4)	31 Aug 2020 17:22:40
	(b) (4)	



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 17:22:40

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Stanley Dublin (b) (4)	31 Aug 2020 17:22:40
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '28 Aug 2020'	Stanley Dublin (b) (4)	31 Aug 2020 17:22:40

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '0'	Stanley Doublin (b) (4) (b) (4)	31 Aug 2020 17:22:40

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)' reason for change: Data Entry Error	Joan Siegner (b) (4)	14 Sep 2020 19:09:10
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	31 Aug 2020 17:22:40

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:07:52
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:32:02
	(b) (4)	
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:32:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '4 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	14 Sep 2020 19:09:10
User entered empty.	Stanley Dublin (b) (4)	31 Aug 2020 17:22:40
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Stanley Doublin (b) (4)	31 Aug 2020 17:22:40

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User entered '3'	System	31 Aug 2020 17:22:40



US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User entered 'I'	System	31 Aug 2020 17:22:40

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:27
User entered '804 (804)'	System	31 Aug 2020 17:22:40

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 05:39:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 05:39:37
Data point term sent to Coder	System	08 Apr 2021 20:14:26
Coding entries removed.	Heather Douds (b) (4)	08 Apr 2021 20:14:02
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User closed query 'Please add metoclopramide for nausea /vomiting , 1-2 tables as needed and prescribed during hospital stay .' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 19:38:44
Query 'Please add metoclopramide for nausea /vomiting , 1-2 tables as needed and prescribed during hospital stay .' answered with 'Per subject, did not take metoclopramide' (Site from CRA).	Heather Douds (b) (4)	05 Oct 2020 13:54:16
User opened query 'Please add metoclopramide for nausea /vomiting , 1-2 tables as needed and prescribed during hospital stay .' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 14:30:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 16:03:40

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	17 Sep 2020 16:03:40
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	17 Sep 2020 16:02:50
User entered 'Zofran'	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:27:09
DataPoint Un-verified.	Heather Douds (b) (4)	08 Apr 2021 20:14:02
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	08 Apr 2021 20:14:02
	(b) (4)	
User entered 'NAUSEA, intractable vomiting'	Heather Douds (b) (4)	08 Apr 2021 20:14:02
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'nausea'	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '4'	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'mg (mg)'	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'once (ONCE)'	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Intravenous (INTRAVENOUS)'	Heather Douds (b) (4) (b) (4)	17 Sep 2020 16:02:30

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '16 Sep 2020'	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '0'	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Heather Douds (b) (4)	17 Sep 2020 16:02:30
	(b) (4)	



**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:08:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '16 Sep 2020'	Heather Douds (b) (4)	17 Sep 2020 16:02:30

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 17:36:45
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:17:07
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:48:59
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	01 Feb 2021 16:47:00
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	01 Feb 2021 16:46:56
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	01 Feb 2021 16:46:56
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 07:18:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:22
User closed query 'Please update to No. Medication is taken for Nausea, which is unsolicited event. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:15:20
Query 'Please update to No. Medication is taken for Nausea, which is unsolicited event. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	24 Nov 2020 17:13:44
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	24 Nov 2020 17:13:23
User entered 'No (N)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	24 Nov 2020 17:13:23
User opened query 'Please update to No. Medication is taken for Nausea, which is unsolicited event. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:47:06

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	17 Sep 2020 16:02:30

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User entered empty.	System	17 Sep 2020 16:02:30

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User entered empty.	System	17 Sep 2020 16:02:30

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:30
User entered empty.	System	17 Sep 2020 16:02:30

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 05:44:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 05:44:37
Data point term sent to Coder	System	08 Apr 2021 20:14:26
Coding entries removed.	Heather Douds (b) (4)	08 Apr 2021 20:14:09
User signature succeeded.	(b) (4)	
	sharon frey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Please capture IV fluids during hospitalization. ' (Site from CRA).	(b) (4)	
Query 'Please capture IV fluids during hospitalization. ' answered with 'type of fluid, rate of fluids, and volume of fluids unknown' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 17:11:54
	Heather Douds (b) (4)	28 Oct 2020 18:36:02
User opened query 'Please capture IV fluids during hospitalization. ' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:43
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 17:59:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 17:59:18
Data point term sent to Coder	System	07 Oct 2020 17:58:04

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:08:15**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'zofran'	Heather Douds (b) (4) (b) (4)	07 Oct 2020 17:57:35



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:27:12
DataPoint Un-verified.	Heather Douds (b) (4)	08 Apr 2021 20:14:09
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	08 Apr 2021 20:14:09
	(b) (4)	
User entered 'NAUSEA, intractable vomiting'	Heather Douds (b) (4)	08 Apr 2021 20:14:09
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'nausea'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:19:45
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	Heather Douds (b) (4)	12 Nov 2020 20:30:16
' answered with 'actual dose not available, self reported' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	12 Nov 2020 17:02:59
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'I'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'tablet (TABLET)'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'once (ONCE)'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:08:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'Oral (ORAL)'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered empty.	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '18 Sep 2020'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '0'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered '18 Sep 2020'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:46
User entered 'No (N)'	Heather Douds (b) (4)	07 Oct 2020 17:57:35
	(b) (4)	

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:08:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User entered empty.	System	07 Oct 2020 17:57:35

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User entered empty.	System	07 Oct 2020 17:57:35



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:33
User entered empty.	System	07 Oct 2020 17:57:35

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 09:55:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 09:55:46
Data point term sent to Coder	System	08 Apr 2021 20:14:27
Coding entries removed.	Heather Douds (b) (4)	08 Apr 2021 20:14:15
User signature succeeded.	(b) (4) sharon frey (b) (4)	21 Feb 2021 17:36:45
User closed query 'Please confirm is subject was taking diphenhydramine, metoclopramide, ondasetron, as indicated in Active mediations section PCP note page 4. Thank you! ' (Site from CRA).	(b) (4) (u) (4), (b) (6)	16 Nov 2020 03:10:13
Query 'Please confirm is subject was taking diphenhydramine, metoclopramide, ondasetron, as indicated in Active mediations section PCP note page 4. Thank you! ' answered with 'Please see source documents which stated that we confirmed multiple times with the subject that she only took the medications listed on the con med page, thanks' (Site from CRA).	Heather Douds (b) (4)	13 Nov 2020 16:13:04
User opened query 'Please confirm is subject was taking diphenhydramine, metoclopramide, ondasetron, as indicated in Active mediations section PCP note page 4. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 21:57:51
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:52:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:12:16

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'IV fluids'	Coder Import (b) (4) (b) (4) System Heather Douds (b) (4) (b) (4)	29 Oct 2020 21:12:16  28 Oct 2020 18:37:23 28 Oct 2020 18:36:46

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:13
User entered 'No (N)'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 17:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:27:15
DataPoint Un-verified.	Heather Douds (b) (4)	08 Apr 2021 20:14:15
	(b) (4)	
Signature has been broken.	Heather Douds (b) (4)	08 Apr 2021 20:14:15
	(b) (4)	
User entered 'NAUSEA, intractable vomiting'	Heather Douds (b) (4)	08 Apr 2021 20:14:15
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:52:15
User entered 'nausea'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:17
User entered 'unknown'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:18
User entered 'Other (OTHER)'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:20
User entered 'unknown'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:22
User entered 'unknown (UNKNOWN)'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:52:24
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 18:36:46

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:25
User entered 'Intravenous (INTRAVENOUS)'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:27
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:28
User entered '17 Sep 2020'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:30
User entered '0'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:31
User entered 'No (N)'	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:08:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:52:33
User entered '18 Sep 2020'	Heather Douds (b) (4)	28 Oct 2020 18:36:46



US3552053

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:52:34
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 18:36:50
User entered 'Yes (Y)'	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 18:36:46
	(b) (4)	

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:08:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User entered empty.	System	28 Oct 2020 18:36:46

US3552053

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User entered empty.	System	28 Oct 2020 18:36:46

**US3552053**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:08:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:35
User entered empty.	System	28 Oct 2020 18:36:46

US3552053

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:08:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:08:10
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:32:10

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17



**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:50:39
User entered '18/Sep/2020 13:48'	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:50:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
User entered 'l'	(b) (4), (b) (6)	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17



**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:50:46
User entered '22/Sep/2020 09:05'	System	22 Sep 2020 13:05:23



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:50:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 18:49:49
User entered 'l'	(b) (4), (b) (6)	22 Sep 2020 13:05:23

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Site Address: [Street](#)**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:50:51
User entered '28/Sep/2020 07:59'	System	28 Sep 2020 11:59:46

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:50:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 18:49:49
User entered 'l'	(b) (4), (b) (6)	28 Sep 2020 11:59:46

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:50:58
User entered '29/Sep/2020 14:50'	System	29 Sep 2020 18:50:13

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:50:59
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:20:42
User entered 'l'	(b) (4), (b) (6)	29 Sep 2020 18:50:13

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Site Address: [Street](#)**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:03
User entered '06/Oct/2020 13:20'	System	06 Oct 2020 13:20:54

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:34:52
User entered 'l'	(b) (4), (b) (6)	06 Oct 2020 13:20:54

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17



**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:09
User entered '12/Oct/2020 12:35'	System	12 Oct 2020 12:35:07



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 21:25:33
User entered 'l'	(b) (4), (b) (6)	12 Oct 2020 12:35:07

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:14
User entered '12/Oct/2020 17:32'	System	12 Oct 2020 21:32:34

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:04:47
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 21:32:34
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 21:25:48

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17



**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:20
User entered '14/Oct/2020 13:04'	System	14 Oct 2020 13:05:02

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:06:55
User entered 'l'	(b) (4), (b) (6)	14 Oct 2020 13:05:02

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:25
User entered '15/Oct/2020 08:07'	System	15 Oct 2020 12:07:04

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 16:39:49
User entered 'l'	(b) (4), (b) (6)	15 Oct 2020 12:07:04

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:14
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'USA-US089-2020-MRNA-1273-P301000003'	System	18 Sep 2020 17:46:17



**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:17
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:19
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:20
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:22
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:23
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:25
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'No (N)'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'sharon'	System	18 Sep 2020 17:46:17



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'frey'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:22
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:24
User entered 'St. Louis'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 17:48:09
User entered 'MO'	System	18 Sep 2020 17:46:17

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:25
User entered '63104'	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:31:31

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:08:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:45:31
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:05:10
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:41:52
User entered 'US' (non-conformant).	System	18 Sep 2020 17:48:16

US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
User entered '10'	(b) (4)	21 Oct 2020 16:40:33
User entered '9'	System	15 Oct 2020 12:07:04
User entered '8'	System	14 Oct 2020 13:05:02
User entered '7'	System	12 Oct 2020 21:32:34
User entered '6'	System	12 Oct 2020 12:35:07
User entered '5'	System	06 Oct 2020 13:20:54
User entered '4'	System	29 Sep 2020 18:50:13
User entered '3'	System	28 Sep 2020 11:59:46
User entered '2'	System	22 Sep 2020 13:05:23
User entered '1'	System	18 Sep 2020 17:48:16

**US3552053**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (10)**

**Generated On: 10 Jun 2021 08:08:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:31
User entered '21/Oct/2020 16:40'	System	21 Oct 2020 16:40:33



US3552053

Folder: SAE USA-US089-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:08:15

**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.	sharon frey (b) (4)	21 Feb 2021 17:36:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:51:32
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 16:42:32
User entered 'l'	(b) (4), (b) (6)	21 Oct 2020 16:40:33