

US3552386 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:16:43

All time stamps listed in this document are displayed in GMT

US3552386

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

---

Participant ID

US3552386

---

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

---

---

US3552386

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3552386

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	True
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3552386

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Date of Informed Consent ( <i>dd MMM yyyy</i> )	09 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3552386

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3552386

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

---

Were any significant conditions reported?

Yes ☒  
No ☐

---

US3552386

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	SEIZURES
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3552386

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	SEASONAL ALLERGIES
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)	_____

US3552386

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	GENERALIZED MYALGIA
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552386

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	TRANSIENT ISCHEMIC ATTACK
Start date (dd MMM yyyy)	UN UNK 2003
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3552386

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	HEART PALPITATIONS
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552386

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	IRRITABLE BOWEL SYNDROME
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)	_____

US3552386

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	MIGRAINES WITH AURA
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)	_____

US3552386

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	ANEMIA
Start date (dd MMM yyyy)	UN NOV 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 FEB 2019
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	FEB 2019
Stop Year (derived)	2019

US3552386

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

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



US3552386

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	ALLERGY TO LATEX
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552386

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

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

US3552386

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	DYSFUNCTIONAL UTERINE BLEEDING
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3552386

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

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

US3552386

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Condition	HYPEROPIA
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)	

US3552386

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 SEP 2020
Time of assessment (00:00-23:59)	14:23 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:23
Height (xxx.x)	67 in
Weight (xxx.x)	150.4 lb
BMI (xxx.x)	23.60522 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)	

US3552386

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3552386

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*) 09 SEP 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 2010

Date of surgery unknown False

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

Date of last menstruation unknown False



US3552386

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

---

**Specify**

US3552386

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

CLASS EVERYDAY; GROCERY  
SHOPPING; OUTDOOR DINING;  
SOCIALIZING WITH FAMILY;  
BOYFRIEND WORKS AT  
OFFICE; OWNS PROPERTY +  
VISITS RENTER + FRIENDS  
WITHOUT MASKS  
FREQUENTLY; STORES - LOWES

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

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

US3552386

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3552386

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 112883

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 ☒

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Height	ND - Not Done
Weight	ND - Not Done

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

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)	09 SEP 2020
Time of assessment (00:00-23:59)	14:23 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:23
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

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)	09 SEP 2020
Time of assessment (00:00-23:59)	16:03 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 16:03
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3552386

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

---

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.*

---



US3552386

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

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) 09 SEP 2020

What was the treatment time? (00:00-23:59) 15:33 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 15:33

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

US3552386

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	15:05 (24 HR)
Collection date and time (derived)	9 SEP 2020 15:05

US3552386

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:08	9 SEP 2020 15:08
Nasopharyngeal Swab 2	No		

US3552386

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:30

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**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

09 SEP 2020 16:02

PC Open Date & Time

09 SEP 2020 15:53

PC Close Date & Time

09 SEP 2020 18:23

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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	10 SEP 2020 06:29
PC Open Date & Time	09 SEP 2020 19:18
PC Close Date & Time	10 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 06:01

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:03

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

12 SEP 2020 12:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 17:53

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 06:27

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 18:31

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**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

09 SEP 2020 16:02

PC Open Date & Time

09 SEP 2020 15:53

PC Close Date & Time

09 SEP 2020 18:23

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 06:30

PC Open Date & Time

09 SEP 2020 19:18

PC Close Date & Time

10 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 06:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**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

11 SEP 2020 18:04

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**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

12 SEP 2020 12:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**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

13 SEP 2020 17:53

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**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

15 SEP 2020 06:27

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**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

15 SEP 2020 18:32

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**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 ☐

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 16:03
PC Open Date & Time	09 SEP 2020 15:53
PC Close Date & Time	09 SEP 2020 18:23

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**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 ☐

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 06:30
PC Open Date & Time	09 SEP 2020 19:18
PC Close Date & Time	10 SEP 2020 11:59



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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

56 of 2130

EAB) (1725)

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 06:02
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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

58 of 2130

EAB) (1725)

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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

60 of 2130

EAB) (1725)

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:03
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2130

EAB) (1725)

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:54
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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

64 of 2130

EAB) (1725)

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 06:27
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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

66 of 2130

EAB) (1725)

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

		Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 18:32	
PC Open Date & Time	15 SEP 2020 12:00	
PC Close Date & Time	16 SEP 2020 11:59	

US3552386

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3552386

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:55
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	16:07 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 16:07
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3552386

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:37 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 15:37

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

US3552386

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

15:09 (24 HR)

Collection date and time (derived)

13 OCT 2020 15:09



US3552386

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:11	13 OCT 2020 15:11
Nasopharyngeal Swab 2	No		

US3552386

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 16:06

PC Open Date & Time

13 OCT 2020 15:57

PC Close Date & Time

13 OCT 2020 18:27

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	14 OCT 2020 05:11
PC Open Date & Time	13 OCT 2020 19:22
PC Close Date & Time	14 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

15 OCT 2020 00:00

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 12:15

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

16 OCT 2020 12:11

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**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

98.5 °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

18 OCT 2020 10:22

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59



US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**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

98.3 °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

18 OCT 2020 12:01

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 12:01

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 16:07

PC Open Date & Time

13 OCT 2020 15:57

PC Close Date & Time

13 OCT 2020 18:27

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**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 OCT 2020 05:12

PC Open Date & Time

13 OCT 2020 19:22

PC Close Date & Time

14 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**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 OCT 2020 00:01

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 12:15

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 12:11

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**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 OCT 2020 10:22

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59



US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**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

18 OCT 2020 12:01

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 12:02

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**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 ☐

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 16:08
PC Open Date & Time	13 OCT 2020 15:57
PC Close Date & Time	13 OCT 2020 18:27

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**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 ☐

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 05:12
PC Open Date & Time	13 OCT 2020 19:22
PC Close Date & Time	14 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

102 of 2130

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 00:01
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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

104 of 2130

EAB) (1725)

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**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)

106 of 2130

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

108 of 2130

EAB) (1725)

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 10:23
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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)

110 of 2130

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 12:02
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

112 of 2130

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 12:02
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3552386

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3552386

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

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) \_\_\_\_\_

US3552386

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

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.*

US3552386

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 NOV 2020
Collection time (00:00-23:59)	15:39 (24 HR)
Collection date and time (derived)	10 NOV 2020 15:39

US3552386

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:51

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

<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	12 NOV 2020 20:13:34
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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 <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	17 NOV 2020 20:06:05
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 20:24:28
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59



US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 04:47:34

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 05:15:31

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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	12 DEC 2020 21:39:30
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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

18 DEC 2020 10:21:43

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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	28 DEC 2020 12:58:24
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 00:02:27
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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	08 JAN 2021 08:54:46
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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

15 JAN 2021 06:19:10

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59



US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 06:05:24

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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

02 FEB 2021 14:18:49

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 13:38:27

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

<b>TIMEPOINT</b>	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 19:52:32
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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

19 FEB 2021 05:21:50

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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

26 FEB 2021 07:09:09

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 05:59:33

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 19:52:14

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59



US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 08:05:49

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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

26 MAR 2021 06:39:49

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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

02 APR 2021 08:23:23

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 19:31:19

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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

16 APR 2021 19:30:46

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 17:05:22

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 19:32:56

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 MAY 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 MAY 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

06 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 AUG 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 AUG 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

22 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 OCT 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

26 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 NOV 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

17 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

21 DEC 2021 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 FEB 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

11 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 FEB 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 MAR 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 MAR 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 MAY 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐ 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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

20 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 MAY 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 MAY 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

10 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 JUN 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

22 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 JUL 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

05 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

09 AUG 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐ 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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 SEP 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2022 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59
---	-------------------

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 NOV 2022 23:59

---

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**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 ☐

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

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"/>

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

---

US3552386

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:16:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 05:25:05



US3552386

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:39:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:39:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3552386

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 APR 2021
Time of assessment (00:00-23:59)	16:03 (24 HR)
Vital Signs Date and Time (derived)	09 APR 2021 16:03
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552386

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 APR 2021

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

US3552386

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 APR 2021

Collection time (00:00-23:59)

16:16 (24 HR)

Collection date and time (derived)

09 APR 2021 16:16

US3552386

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3552386**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:16:43**

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*

**US3552386**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:43**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552386

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:16:43

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"/>



**US3552386**

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

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

**Generated On: 10 Jun 2021 08:16:43**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3552386

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3552386

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:39:29

Generated On: 10 Jun 2021 08:16:43

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3552386

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

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

US3552386

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:15
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3552386

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 12:10
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3552386

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

14 JAN 2021

---

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

---

US3552386

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 11:35

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



US3552386

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	11:02 (24 HR)
Collection date and time (derived)	14 JAN 2021 11:02

US3552386

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	10:55
Collection Date and Time (derived)	14 JAN 2021 10:55

US3552386

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag	1
-----------------	---

OLD29 Placebo Flag	1
--------------------	---

US3552386

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 03:30:28

Generated On: 10 Jun 2021 08:16:43

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)	08 FEB 2021
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 13:50
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	164 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 03:30:28

Generated On: 10 Jun 2021 08:16:43

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)	08 FEB 2021
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 14:50
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG



US3552386

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 FEB 2021

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

US3552386

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 08 FEB 2021

What was the treatment time? (00:00-23:59) 14:20 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 14:20

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

What was the frequency of the study treatment dosing? ONCE

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

US3552386

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552386

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:03:29

Generated On: 10 Jun 2021 08:16:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552386

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 15:39:24

Generated On: 10 Jun 2021 08:16:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	OLD57

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 15:39:29

Generated On: 10 Jun 2021 08:16:43

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) \_\_\_\_\_

US3552386

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 15:39:24

Generated On: 10 Jun 2021 08:16:43

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.*



US3552386

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 15:39:24

Generated On: 10 Jun 2021 08:16:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 MAR 2021
Collection time (00:00-23:59)	13:56 (24 HR)
Collection date and time (derived)	12 MAR 2021 13:56

US3552386

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 18:03:24

Generated On: 10 Jun 2021 08:16:43

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

AEID	USA-US089-2021-MRNA-1273-P30 1000009
Adverse event	RIGHT EYE RETINAL TEAR
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)	29 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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	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)

354 of 2130

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

---

SUBJECT WENT TO URGENT  
CARE FOR NEW FLOATER IN  
RIGHT EYE, IMMEDIATELY  
SENT TO HOSPITAL FOR  
SUSPECTED RETINAL TEAR.  
WAS NOT ADMITTED TO  
HOSPITAL, WAITED IN ED  
BEFORE RETINAL TEAR REPAIR  
SURGERY EARLY MORNING OF  
31MAR. MEDICAL RECORDS  
REQUESTED ON 09APR, WILL  
UPDATE ONCE OBTAINED.  
UPDATE 4/12 - REPAIR ON  
31MAR WAS A LASER  
RETINOPEXY; NO OCULAR  
MEDS PRESCRIBED ASIDE  
FROM THOSE GIVEN FOR EXAM  
IN ED. WILL SEND MEDICAL  
RECORDS TO MEDICAL  
MONITOR.

---

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

---

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 19:03:28

Generated On: 10 Jun 2021 08:16:43

---

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

Yes ☒

No ☐

---

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

---

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Name of Medication TRILEPTAL

Prophylaxis Yes ☐  
No ☒

Indication SEIZURES

Dose per administration 300

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)

358 of 2130

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Name of Medication FLONASE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 2

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

If dose unit is Other, specify SPRAY

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)

360 of 2130

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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	1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Name of Medication ALLEGRA

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

362 of 2130

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH PROMOTION

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

364 of 2130

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED MYALGIA

Dose per administration 1000

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

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

366 of 2130

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

	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 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 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"/>



US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Name of Medication VITAMIN D + CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication HEALTH PROMOTION

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

368 of 2130

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 OCT 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

370 of 2130

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Name of Medication MYDRIACYL 1.0%

Prophylaxis Yes ☐  
No ☒

Indication RETINAL TEAR R EYE

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

372 of 2130

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 31 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Name of Medication 2.5% EPINEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication RETINAL TEAR R EYE

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

374 of 2130

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 31 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3552386

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3552386

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 18:03:25

Generated On: 10 Jun 2021 08:16:43

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
31 MAR 2021	LASER RETINOPEXY R EYE	Adverse Event	

US3552386

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:16:43

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

US3552386

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:43

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 ☐

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 20 Apr 2021 19:41:04

Generated On: 10 Jun 2021 08:16:43

SAEID	USA-US089-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Apr 2021 19:41:04

Generated On: 10 Jun 2021 08:16:43

SAEID	USA-US089-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 14:42
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

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Apr 2021 19:41:04

Generated On: 10 Jun 2021 08:16:43

SAEID	USA-US089-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/APR/2021 09:15
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.	True

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 20 Apr 2021 19:41:04

Generated On: 10 Jun 2021 08:16:43

SAEID	USA-US089-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/APR/2021 09:50
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



US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 20 Apr 2021 19:41:04

Generated On: 10 Jun 2021 08:16:43

SAEID	USA-US089-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/APR/2021 15:16
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

US3552386 (Prod: Saint Louis University)

**US3552386**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:16:43**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'US3552386'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 19:34:26

US3552386

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:09

US3552386

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 19:34:27

US3552386

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:09

**US3552386**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'SCRN'	System	10 Sep 2020 14:13:09

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 19:34:28



US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '57'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'YEARS'	System	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '57'	System	09 Sep 2020 20:11:06

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Female (F)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Mikayla Frye (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35



US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'I'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:35

US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '09 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 15:45:28
User entered '9 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:11:06

US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Sep 2020'	System	09 Sep 2020 20:11:06



US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2020'	System	09 Sep 2020 20:11:06

US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Amendment 3 (3)'	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:11:06

US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:11:06

US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:11:06

US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	09 Sep 2020 20:11:06

US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:11:06

US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 19:34:27

US3552386

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'l'	System	09 Sep 2020 20:11:12



US3552386

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:11:12

US3552386

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:16:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:13:42

US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizures - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:15:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:15:41
Data point term sent to Coder	System	10 Sep 2020 14:14:52
User entered 'seizures'	Mikayla Frye (b) (4)	10 Sep 2020 14:14:05

US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 1985'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:05

US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:05

US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:05

US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:05

US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:05



US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 1985'	System	10 Sep 2020 14:14:05

US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '1985'	System	10 Sep 2020 14:14:05

US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:14:05

US3552386

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:14:05

US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:15:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:15:41
Data point term sent to Coder	System	10 Sep 2020 14:14:52
User entered 'seasonal allergies'	Mikayla Frye (b) (4)	10 Sep 2020 14:14:18
	(b) (4)	

US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 1989'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:18

US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:18

US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:18



US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:18

US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:18

US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 1989'	System	10 Sep 2020 14:14:18

US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '1989'	System	10 Sep 2020 14:14:18

US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:14:18

US3552386

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:14:18

US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User closed query 'Per DM CLR: Please specify the type and/or location of MYALGIA. 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) (4), (b) (6)	27 Oct 2020 09:35:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 15:53:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 15:53:11
Data point term sent to Coder	System	26 Oct 2020 15:25:02
Query 'Per DM CLR: Please specify the type and/or location of MYALGIA. 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 'resolved' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:24:30
Coding entries removed.		26 Oct 2020 15:24:23
User entered 'Generalized MYALGIA' reason for change: Data Entry Error		26 Oct 2020 15:24:23
User opened query 'Per DM CLR: Please specify the type and/or location of MYALGIA. 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).		23 Oct 2020 14:50:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:21:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:21:12
Data point term sent to Coder	System	10 Sep 2020 16:19:12
Coding entries removed.	Heather Douds (b) (4) (b) (4)	10 Sep 2020 16:18:45

US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
User entered 'Myalgia' reason for change: Data Entry Error	Heather Douds (b) (4)	10 Sep 2020 16:18:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle soreness - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:15:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:15:41
Data point term sent to Coder	System	10 Sep 2020 14:14:52
User entered 'muscle soreness'	Mikayla Frye (b) (4)	10 Sep 2020 14:14:34



US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 1980'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:34

US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:34

US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:34

US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:34

US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:14:34

US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 1980'	System	10 Sep 2020 14:14:34

US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '1980'	System	10 Sep 2020 14:14:34

US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:14:34



US3552386

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:14:34

US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:16:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 14:16:39
Data point term sent to Coder	System	10 Sep 2020 14:15:54
User entered 'transient ischemic attack'	Mikayla Frye (b) (4)	10 Sep 2020 14:15:11
	(b) (4)	

US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2003'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:11

US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:11

US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:11

US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User closed query 'Per DM CLR: Please review the status of this condition as the effects of the TRANSIENT ISCHEMIC ATTACK may be longer but the condition itself is not.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the status of this condition as the effects of the TRANSIENT ISCHEMIC ATTACK may be longer but the condition itself is not.' answered with 'No residual symptoms. Entered correctly. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:21:25
Query 'Per DM CLR: Please review the status of this condition as the effects of the TRANSIENT ISCHEMIC ATTACK may be longer but the condition itself is not.' answered with 'No residual symptoms. Entered correctly. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4)	06 Oct 2020 15:53:03
User opened query 'Per DM CLR: Please review the status of this condition as the effects of the TRANSIENT ISCHEMIC ATTACK may be longer but the condition itself is not.' (Site from DM).	(b) (4)	
User entered 'un UNK 2004'	(b) (4), (b) (6)	06 Oct 2020 06:42:03
	Mikayla Frye (b) (4)	10 Sep 2020 14:15:11
	(b) (4)	

US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:11

US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 2003'	System	10 Sep 2020 14:15:11



US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2003'	System	10 Sep 2020 14:15:11

US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 2004'	System	10 Sep 2020 14:15:11

US3552386

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2004'	System	10 Sep 2020 14:15:11

US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac signs and symptoms NEC, PT: Palpitations, LLT: Palpitations - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:16:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:16:40
Data point term sent to Coder	System	10 Sep 2020 14:15:55
User entered 'heart palpitations'	Mikayla Frye (b) (4)	10 Sep 2020 14:15:23

US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2012'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:23

US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:23

US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:23

US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:23



US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:23

US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 2012'	System	10 Sep 2020 14:15:23

US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2012'	System	10 Sep 2020 14:15:23

US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:15:23

US3552386

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:15:23

US3552386

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
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.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:16:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:16:40
Data point term sent to Coder	System	10 Sep 2020 14:15:57
User entered 'irritable bowel syndrome'	Mikayla Frye (b) (4)	10 Sep 2020 14:15:34

US3552386

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'UN UNK 1989' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	10 Sep 2020 16:15:28
User entered 'un UNK 2012'	(b) (4)	
	Mikayla Frye (b) (4)	10 Sep 2020 14:15:34
	(b) (4)	

US3552386

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:34



US3552386

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:34

US3552386

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:34

US3552386

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:34

**US3552386**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 1989'	System	10 Sep 2020 16:15:28
User entered 'Jan 2012'	System	10 Sep 2020 14:15:34

**US3552386**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '1989'	System	10 Sep 2020 16:15:28
User entered '2012'	System	10 Sep 2020 14:15:34

US3552386

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:15:34

US3552386

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:15:34

US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine with aura, LLT: Migraine with aura - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:16:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:16:40
Data point term sent to Coder	System	10 Sep 2020 14:15:55
User entered 'migraines with aura'	Mikayla Frye (b) (4)	10 Sep 2020 14:15:46
	(b) (4)	



US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 1989'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:46

US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:46

US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:46

US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:46

US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:15:46

US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 1989'	System	10 Sep 2020 14:15:46

US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '1989'	System	10 Sep 2020 14:15:46

US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:15:46



US3552386

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:15:46

US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - 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 Sep 2020 14:17:45
Data point term sent to Coder	(b) (4)	
User entered 'anemia'	Coder Import (b) (4)	10 Sep 2020 14:17:45
	(b) (4)	
	System	10 Sep 2020 14:16:58
	Mikayla Frye (b) (4)	10 Sep 2020 14:16:10
	(b) (4)	

US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un Nov 2018'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:10

US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:10

US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:10

US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un Feb 2019'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:10

US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:10

US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Nov 2018'	System	10 Sep 2020 14:16:10



US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2018'	System	10 Sep 2020 14:16:10

US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Feb 2019'	System	10 Sep 2020 14:16:10

US3552386

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2019'	System	10 Sep 2020 14:16:10

US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:17:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 14:17:45
Data point term sent to Coder	System	10 Sep 2020 14:16:58
User entered 'chronic back pain'	Mikayla Frye (b) (4)	10 Sep 2020 14:16:21

US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2000'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:21

US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:21

US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:21

US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:21



US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:16:21

US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 2000'	System	10 Sep 2020 14:16:21

US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2000'	System	10 Sep 2020 14:16:21

US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:16:21

US3552386

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:16:21

US3552386

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:21:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 14:21:42
Data point term sent to Coder	System	10 Sep 2020 14:20:04
User entered 'allergy to latex'	Mikayla Frye (b) (4)	10 Sep 2020 14:19:34
	(b) (4)	

US3552386

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 1988'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:19:34

US3552386

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:19:34



US3552386

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:19:34

US3552386

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:19:34

US3552386

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:19:34

US3552386

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 1988'	System	10 Sep 2020 14:19:34

**US3552386**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:16:43**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '1988'	System	10 Sep 2020 14:19:34

US3552386

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:19:34

US3552386

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	10 Sep 2020 14:19:34

US3552386

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
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) (4), (b) (6)	13 Oct 2020 11:47:58
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 'data pending at this time' (Site from DM).	Heather Douds (b) (4) (b) (4)	05 Oct 2020 15:15:37
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)	03 Oct 2020 10:10:58
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) (b) (4)	10 Sep 2020 14:21:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:21:43
Data point term sent to Coder	System	10 Sep 2020 14:21:06
User entered 'hysterectomy'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:20:33



US3552386

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2010'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:20:33

US3552386

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:20:33

US3552386

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:20:33

US3552386

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2010'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:20:33

US3552386

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:20:33

US3552386

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 2010'	System	10 Sep 2020 14:20:33

**US3552386**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:16:43**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2010'	System	10 Sep 2020 14:20:33

US3552386

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 2010'	System	10 Sep 2020 14:20:33



US3552386

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:16:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2010'	System	10 Sep 2020 14:20:33

US3552386

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysfunctional uterine bleeding, LLT: Dysfunctional uterine bleeding - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 13:17:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 13:17:33
Data point term sent to Coder	System	14 Oct 2020 13:16:38
User entered 'dysfunctional uterine bleeding'	Stanley Doublin (b) (4)	14 Oct 2020 13:16:01

US3552386

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2010'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 13:16:01

US3552386

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 13:16:01

US3552386

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 13:16:01

US3552386

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2010'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 13:16:01

US3552386

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 13:16:01

US3552386

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 2010'	System	14 Oct 2020 13:16:01



**US3552386**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:16:43**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2010'	System	14 Oct 2020 13:16:01

US3552386

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:16:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'Jan 2010'	System	14 Oct 2020 13:16:01

**US3552386**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:16:43**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '2010'	System	14 Oct 2020 13:16:01

US3552386

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User coded data point as SOC: Eye disorders, HLGT: Ocular neuromuscular disorders, HLT: Ocular nerve and muscle disorders, PT: Strabismus, LLT: Strabismus - version MedDRA\\23.0.	(b) (4) Codor Import (b) (4)	12 Apr 2021 15:00:06
User coded data point as Term Coded data point by User: Codor System - version MedDRA\\23.0.	Codor Import (b) (4)	12 Apr 2021 15:00:06
Data point term sent to Codor System	System	12 Apr 2021 14:59:17
User entered 'strabismus'	Heather Douds (b) (4)	12 Apr 2021 14:58:50
	(b) (4)	

US3552386

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered empty.	(b) (4) Heather Douds (b) (4)	12 Apr 2021 14:58:50

US3552386

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'l'	(b) (4) Heather Douds (b) (4)	12 Apr 2021 14:58:50

US3552386

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	12 Apr 2021 14:58:50

US3552386

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered empty.	(b) (4) Heather Douds (b) (4)	12 Apr 2021 14:58:50



US3552386

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'l'	(b) (4) Heather Douds (b) (4)	12 Apr 2021 14:58:50

US3552386

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:16:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	12 Apr 2021 14:58:50

**US3552386**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:16:43**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	12 Apr 2021 14:58:50

**US3552386**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:16:43**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	12 Apr 2021 14:58:50

**US3552386**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:16:43**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	12 Apr 2021 14:58:50

US3552386

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:16:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	12 Apr 2021 15:00:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 15:00:04
Data point term sent to Coder	System	12 Apr 2021 14:59:18
User entered 'hyperopia'	Heather Douds (b) (4)	12 Apr 2021 14:59:01
	(b) (4)	

US3552386

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:16:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered empty.	(b) (4) Heather Douds (b) (4)	12 Apr 2021 14:59:01

US3552386

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	12 Apr 2021 14:59:01



US3552386

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:16:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	12 Apr 2021 14:59:01

US3552386

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:16:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered empty.	(b) (4) Heather Douds (b) (4)	12 Apr 2021 14:59:01

US3552386

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:16:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	12 Apr 2021 14:59:01

**US3552386**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:16:43**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	12 Apr 2021 14:59:01

**US3552386**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:16:43**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	12 Apr 2021 14:59:01

**US3552386**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:16:43**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	12 Apr 2021 14:59:01

**US3552386**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:16:43**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered empty.	System	12 Apr 2021 14:59:01

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:25



US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 15:45:50
User entered '9 Sep 2020'	(b) (4)	
	Mikayla Frye (b) (4)	10 Sep 2020 14:23:25
	(b) (4)	

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14:23'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '09 Sep 2020 14:23'	System	10 Nov 2020 15:45:50
User entered '9 Sep 2020 14:23'	System	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '67' in	(b) (4) Mikayla Frye (b) (4)	10 Sep 2020 14:23:25
DataPoint set to visible.	(b) (4) System	09 Sep 2020 20:11:12

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '150.4' lb	(b) (4) Mikayla Frye (b) (4)	10 Sep 2020 14:23:25
DataPoint set to visible.	(b) (4) System	09 Sep 2020 20:11:12

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered '23.60522'	System	10 Sep 2020 14:23:25
DataPoint set to visible.	System	09 Sep 2020 20:11:12

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'kg/m2'	System	10 Sep 2020 14:23:25
DataPoint set to visible.	System	09 Sep 2020 20:11:12

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:25



US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'bpm'	System	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'breaths/min'	System	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'mmHg'	System	10 Sep 2020 14:23:25



US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User entered 'mmHg'	System	10 Sep 2020 14:23:25

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52

US3552386

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52

US3552386

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:23:32

US3552386

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 15:45:58
User entered '9 Sep 2020'	(b) (4)	
	Mikayla Frye (b) (4)	10 Sep 2020 14:23:32
	(b) (4)	

US3552386

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 15:46:05
User entered '9 Sep 2020'	(b) (4)	
	Mikayla Frye (b) (4)	10 Sep 2020 14:22:48
	(b) (4)	

US3552386

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:43

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:22:48



US3552386

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:43

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) Mikayla Frye (b) (4)	10 Sep 2020 14:22:48

US3552386

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:43

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:22:48

US3552386

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2010'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:22:48

US3552386

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:43

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:22:48

US3552386

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:22:48

US3552386

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:43

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:22:48

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56



US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

**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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

**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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

[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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

**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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

**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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

[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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

**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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56



US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

**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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'class everyday; grocery shopping; outdoor dining; socializing with family; boyfriend works at office; owns property + visits renter + friends without masks frequently; stores - Lowes'	(b) (4) Mikayla Frye (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

**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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

**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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

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)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56



US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'l'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:24:56

US3552386

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:25:17

US3552386

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '09 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 15:46:17
User entered '9 Sep 2020'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:25:17

US3552386

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[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 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:25:17

US3552386

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'VISIT1'	System	10 Sep 2020 14:25:17

US3552386

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:09:41



US3552386

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:43

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '112883'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:09:41

US3552386

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:43

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 20:09:41

US3552386

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:43

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 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:25:34

US3552386

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:43

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 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:25:34

US3552386

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:43

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:25:34

US3552386

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:43

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:25:34

US3552386

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:25:34

US3552386

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:43

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4)	21 Sep 2020 18:06:00
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:52:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:52:57



US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 15:46:31
User entered '9 Sep 2020'	(b) (4)	
	Mikayla Frye (b) (4)	10 Sep 2020 14:26:38
	(b) (4)	

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '14:23'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38



US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '09 Sep 2020 14:23'	System	10 Nov 2020 15:46:31
User entered '9 Sep 2020 14:23'	System	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '98.7' F	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '67'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'bpm'	System	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '16'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'breaths/min'	System	10 Sep 2020 14:26:38



US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '153'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'mmHg'	System	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '88'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'mmHg'	System	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38



US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '09 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 15:46:31
User entered '9 Sep 2020'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '16:03'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '09 Sep 2020 16:03'	System	10 Nov 2020 15:46:31
User entered '9 Sep 2020 16:03'	System	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '98.3' F	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '62'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'bpm'	System	10 Sep 2020 14:26:38



US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '16'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'breaths/min'	System	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '147'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'mmHg'	System	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '90'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'mmHg'	System	10 Sep 2020 14:26:38

US3552386

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:46

US3552386

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:26:46



US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:50:36

US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:50:36

US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

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 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:50:36

US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 20:50:36

US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '09 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 15:46:51
User entered '9 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:50:36

US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '15:33'	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:50:36

US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '09 Sep 2020 15:33'	System	10 Nov 2020 15:46:51
User entered '9 Sep 2020 15:33'	System	09 Sep 2020 20:50:36

US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Left Arm (LEFT ARM)'	Cassandra Zehenny (b) (4) (b) (4)	09 Sep 2020 20:50:36



US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'ONCE'	System	09 Sep 2020 20:50:36

US3552386

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 20:50:36

US3552386

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:24

US3552386

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '9 Sep 2020'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:24

US3552386

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '15:05'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:24

US3552386

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '9 Sep 2020 15:05'	System	10 Sep 2020 14:27:24

US3552386

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '9 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:43

US3552386

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:43



US3552386

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:43

US3552386

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '15:08'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:43

US3552386

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '9 Sep 2020 15:08'	System	10 Sep 2020 14:27:43

US3552386

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:43

US3552386

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:43

US3552386

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:43

**US3552386**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered empty.	System	10 Sep 2020 14:27:43

US3552386

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Joan Siegner (b) (4)	16 Sep 2020 18:24:22



US3552386

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'I'	System	16 Sep 2020 18:24:22

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:01:35', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b5665784-0fb8-4be4-bf73-6f7a65bbaa15'	System	09 Sep 2020 21:02:07
User entered 'Yes (Y)'	System	09 Sep 2020 21:02:07

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:01:43', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b5665784-0fb8-4be4-bf73-6f7a65bbaa15'	System	09 Sep 2020 21:02:07
User entered '98.3'	System	09 Sep 2020 21:02:07

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:01:50', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b5665784-0fb8-4be4-bf73-6f7a65bbaa15'	System	09 Sep 2020 21:02:07
User entered 'No (N)'	System	09 Sep 2020 21:02:07

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:02:04', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b5665784-0fb8-4be4-bf73-6f7a65bbaa15'	System	09 Sep 2020 21:02:07
User entered '09 Sep 2020 16:02'	System	09 Sep 2020 21:02:07

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '09 Sep 2020 15:53'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '09 Sep 2020 18:23'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:29:22', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '0bfdec66-5d75-44de-80b7-438212273b8d'	System	10 Sep 2020 11:29:44
User entered 'Yes (Y)'	System	10 Sep 2020 11:29:44

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:29:29', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '0bfdec66-5d75-44de-80b7-438212273b8d'	System	10 Sep 2020 11:29:44
User entered '98.5'	System	10 Sep 2020 11:29:44

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:29:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '0bfdec66-5d75-44de-80b7-438212273b8d'	System	10 Sep 2020 11:29:44
User entered 'No (N)'	System	10 Sep 2020 11:29:44

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:29:40', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '0bfdec66-5d75-44de-80b7-438212273b8d'	System	10 Sep 2020 11:29:44
User entered '10 Sep 2020 06:29'	System	10 Sep 2020 11:29:44

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '09 Sep 2020 19:18'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 2'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:01:10', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '8a9e22ff-e3f5-4b5b-9a54-c6a7ea5ed7fb'	System	11 Sep 2020 11:01:34
User entered 'Yes (Y)'	System	11 Sep 2020 11:01:34

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:01:22', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '8a9e22ff-e3f5-4b5b-9a54-c6a7ea5ed7fb'	System	11 Sep 2020 11:01:34
User entered '98.2'	System	11 Sep 2020 11:01:34

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:01:25', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '8a9e22ff-e3f5-4b5b-9a54-c6a7ea5ed7fb'	System	11 Sep 2020 11:01:34
User entered 'No (N)'	System	11 Sep 2020 11:01:34

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:01:31', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '8a9e22ff-e3f5-4b5b-9a54-c6a7ea5ed7fb'	System	11 Sep 2020 11:01:34
User entered '11 Sep 2020 06:01'	System	11 Sep 2020 11:01:34

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 3'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:03:23', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '39202a1d-7dd9-447b-beed-015b985fdbb0'	System	11 Sep 2020 23:03:50
User entered 'Yes (Y)'	System	11 Sep 2020 23:03:50



US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:03:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '39202a1d-7dd9-447b-beed-015b985fdbb0'	System	11 Sep 2020 23:03:50
User entered '98.6'	System	11 Sep 2020 23:03:50

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:03:38', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '39202a1d-7dd9-447b-beed-015b985fdbb0'	System	11 Sep 2020 23:03:50
User entered 'No (N)'	System	11 Sep 2020 23:03:50

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:03:47', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '39202a1d-7dd9-447b-beed-015b985fdbb0'	System	11 Sep 2020 23:03:50
User entered '11 Sep 2020 18:03'	System	11 Sep 2020 23:03:50

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 4'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:01:57', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '44c2e53c-274d-4b12-ba23-a604090a1335'	System	12 Sep 2020 17:02:59
User entered 'Yes (Y)'	System	12 Sep 2020 17:02:59

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:04', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '44c2e53c-274d-4b12-ba23-a604090a1335'	System	12 Sep 2020 17:02:59
User entered '98.5'	System	12 Sep 2020 17:02:59



US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:06', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '44c2e53c-274d-4b12-ba23-a604090a1335'	System	12 Sep 2020 17:02:59
User entered 'No (N)'	System	12 Sep 2020 17:02:59

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:12', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '44c2e53c-274d-4b12-ba23-a604090a1335'	System	12 Sep 2020 17:02:59
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:02:59

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 5'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:52:50', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'd35609a0-176f-45c5-9992-f8131b963e20'	System	13 Sep 2020 22:53:09
User entered 'Yes (Y)'	System	13 Sep 2020 22:53:09

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:52:57', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'd35609a0-176f-45c5-9992-f8131b963e20'	System	13 Sep 2020 22:53:09
User entered '98.7'	System	13 Sep 2020 22:53:09

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:02', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'd35609a0-176f-45c5-9992-f8131b963e20'	System	13 Sep 2020 22:53:09
User entered 'No (N)'	System	13 Sep 2020 22:53:09



US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:06', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'd35609a0-176f-45c5-9992-f8131b963e20'	System	13 Sep 2020 22:53:09
User entered '13 Sep 2020 17:53'	System	13 Sep 2020 22:53:09

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 6'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:06', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fb290e8a-b2ff-4538-9e32-dde249672240'	System	15 Sep 2020 11:27:22
User entered 'Yes (Y)'	System	15 Sep 2020 11:27:22

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:12', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fb290e8a-b2ff-4538-9e32-dde249672240'	System	15 Sep 2020 11:27:22
User entered '98.2'	System	15 Sep 2020 11:27:22

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:14', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fb290e8a-b2ff-4538-9e32-dde249672240'	System	15 Sep 2020 11:27:22
User entered 'No (N)'	System	15 Sep 2020 11:27:22

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fb290e8a-b2ff-4538-9e32-dde249672240'	System	15 Sep 2020 11:27:22
User entered '15 Sep 2020 06:27'	System	15 Sep 2020 11:27:22



US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 7'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:31:44', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '684576d1-b75e-4d2b-af0f-60aa1c32fdee'	System	15 Sep 2020 23:31:58
User entered 'Yes (Y)'	System	15 Sep 2020 23:31:58

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:31:49', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '684576d1-b75e-4d2b-af0f-60aa1c32fdee'	System	15 Sep 2020 23:31:58
User entered '98.5'	System	15 Sep 2020 23:31:58

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:31:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '684576d1-b75e-4d2b-af0f-60aa1c32fdee'	System	15 Sep 2020 23:31:58
User entered 'No (N)'	System	15 Sep 2020 23:31:58

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:31:56', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '684576d1-b75e-4d2b-af0f-60aa1c32fdee'	System	15 Sep 2020 23:31:58
User entered '15 Sep 2020 18:31'	System	15 Sep 2020 23:31:58

US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:02:27', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '32c117ae-32ad-4ddc-8b86-9de07201733e'	System	09 Sep 2020 21:02:57
User entered 'None (1)'	System	09 Sep 2020 21:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:02:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '32c117ae-32ad-4ddc-8b86-9de07201733e'	System	09 Sep 2020 21:02:57
User entered 'No (N)'	System	09 Sep 2020 21:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:02:39', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '32c117ae-32ad-4ddc-8b86-9de07201733e'	System	09 Sep 2020 21:02:57
User entered 'No (N)'	System	09 Sep 2020 21:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:02:46', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '32c117ae-32ad-4ddc-8b86-9de07201733e'	System	09 Sep 2020 21:02:57
User entered 'None (1)'	System	09 Sep 2020 21:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:02:55', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '32c117ae-32ad-4ddc-8b86-9de07201733e'	System	09 Sep 2020 21:02:57
User entered '09 Sep 2020 16:02'	System	09 Sep 2020 21:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '09 Sep 2020 15:53'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '09 Sep 2020 18:23'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:29:50', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b405d5f2-c87c-4e0d-9c93-1a2cb05c7ef5'	System	10 Sep 2020 11:30:15
User entered 'None (1)'	System	10 Sep 2020 11:30:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:29:58', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b405d5f2-c87c-4e0d-9c93-1a2cb05c7ef5'	System	10 Sep 2020 11:30:15
User entered 'No (N)'	System	10 Sep 2020 11:30:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:01', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b405d5f2-c87c-4e0d-9c93-1a2cb05c7ef5'	System	10 Sep 2020 11:30:15
User entered 'No (N)'	System	10 Sep 2020 11:30:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:06', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b405d5f2-c87c-4e0d-9c93-1a2cb05c7ef5'	System	10 Sep 2020 11:30:15
User entered 'None (1)'	System	10 Sep 2020 11:30:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:12', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b405d5f2-c87c-4e0d-9c93-1a2cb05c7ef5'	System	10 Sep 2020 11:30:15
User entered '10 Sep 2020 06:30'	System	10 Sep 2020 11:30:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '09 Sep 2020 19:18'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 2'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:01:47', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4740eea3-1add-4e1b-9d3e-8b001a0ef7f8'	System	11 Sep 2020 11:02:14
User entered 'None (1)'	System	11 Sep 2020 11:02:14

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:01:51', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4740eea3-1add-4e1b-9d3e-8b001a0ef7f8'	System	11 Sep 2020 11:02:14
User entered 'No (N)'	System	11 Sep 2020 11:02:14

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:01:55', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4740eea3-1add-4e1b-9d3e-8b001a0ef7f8'	System	11 Sep 2020 11:02:14
User entered 'No (N)'	System	11 Sep 2020 11:02:14

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:01:58', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4740eea3-1add-4e1b-9d3e-8b001a0ef7f8'	System	11 Sep 2020 11:02:14
User entered 'None (1)'	System	11 Sep 2020 11:02:14

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:02:09', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4740eea3-1add-4e1b-9d3e-8b001a0ef7f8'	System	11 Sep 2020 11:02:14
User entered '11 Sep 2020 06:02'	System	11 Sep 2020 11:02:14

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 3'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:03:55', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1a71403c-2aff-4fd0-9839-439c5d678052'	System	11 Sep 2020 23:04:20
User entered 'None (1)'	System	11 Sep 2020 23:04:20

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:03:58', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1a71403c-2aff-4fd0-9839-439c5d678052'	System	11 Sep 2020 23:04:20
User entered 'No (N)'	System	11 Sep 2020 23:04:20

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1a71403c-2aff-4fd0-9839-439c5d678052'	System	11 Sep 2020 23:04:20
User entered 'No (N)'	System	11 Sep 2020 23:04:20

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:05', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1a71403c-2aff-4fd0-9839-439c5d678052'	System	11 Sep 2020 23:04:20
User entered 'None (1)'	System	11 Sep 2020 23:04:20

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:16', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1a71403c-2aff-4fd0-9839-439c5d678052'	System	11 Sep 2020 23:04:20
User entered '11 Sep 2020 18:04'	System	11 Sep 2020 23:04:20

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 4'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:17', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1fd71136-4f80-492d-970a-2096ec8d0519'	System	12 Sep 2020 17:03:15
User entered 'None (1)'	System	12 Sep 2020 17:03:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1fd71136-4f80-492d-970a-2096ec8d0519'	System	12 Sep 2020 17:03:15
User entered 'No (N)'	System	12 Sep 2020 17:03:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:21', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1fd71136-4f80-492d-970a-2096ec8d0519'	System	12 Sep 2020 17:03:15
User entered 'No (N)'	System	12 Sep 2020 17:03:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:23', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1fd71136-4f80-492d-970a-2096ec8d0519'	System	12 Sep 2020 17:03:15
User entered 'None (1)'	System	12 Sep 2020 17:03:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:33', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1fd71136-4f80-492d-970a-2096ec8d0519'	System	12 Sep 2020 17:03:15
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:03:15

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 5'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:12', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5f7f8d62-1266-4200-b67d-f8a92224faef'	System	13 Sep 2020 22:53:37
User entered 'None (1)'	System	13 Sep 2020 22:53:37

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:15', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5f7f8d62-1266-4200-b67d-f8a92224faef'	System	13 Sep 2020 22:53:37
User entered 'No (N)'	System	13 Sep 2020 22:53:37

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:17', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5f7f8d62-1266-4200-b67d-f8a92224faef'	System	13 Sep 2020 22:53:37
User entered 'No (N)'	System	13 Sep 2020 22:53:37

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5f7f8d62-1266-4200-b67d-f8a92224faef'	System	13 Sep 2020 22:53:37
User entered 'None (1)'	System	13 Sep 2020 22:53:37

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5f7f8d62-1266-4200-b67d-f8a92224faef' User entered '13 Sep 2020 17:53'	System	13 Sep 2020 22:53:37
	System	13 Sep 2020 22:53:37

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 6'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:25', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'abd98c8d-ee5e-4b57-82d4-0cd806b1d4f3'	System	15 Sep 2020 11:27:39
User entered 'None (1)'	System	15 Sep 2020 11:27:39

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:28', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'abd98c8d-ee5e-4b57-82d4-0cd806b1d4f3'	System	15 Sep 2020 11:27:39
User entered 'No (N)'	System	15 Sep 2020 11:27:39

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'abd98c8d-ee5e-4b57-82d4-0cd806b1d4f3'	System	15 Sep 2020 11:27:39
User entered 'No (N)'	System	15 Sep 2020 11:27:39

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'abd98c8d-ee5e-4b57-82d4-0cd806b1d4f3'	System	15 Sep 2020 11:27:39
User entered 'None (1)'	System	15 Sep 2020 11:27:39

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:35', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'abd98c8d-ee5e-4b57-82d4-0cd806b1d4f3'	System	15 Sep 2020 11:27:39
User entered '15 Sep 2020 06:27'	System	15 Sep 2020 11:27:39

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 7'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04599776-d8be-410e-810d-9e5baa9d11d8'	System	15 Sep 2020 23:32:16
User entered 'None (1)'	System	15 Sep 2020 23:32:16

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:03', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04599776-d8be-410e-810d-9e5baa9d11d8'	System	15 Sep 2020 23:32:16
User entered 'No (N)'	System	15 Sep 2020 23:32:16

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:05', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04599776-d8be-410e-810d-9e5baa9d11d8'	System	15 Sep 2020 23:32:16
User entered 'No (N)'	System	15 Sep 2020 23:32:16

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:07', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04599776-d8be-410e-810d-9e5baa9d11d8'	System	15 Sep 2020 23:32:16
User entered 'None (1)'	System	15 Sep 2020 23:32:16

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:13', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04599776-d8be-410e-810d-9e5baa9d11d8'	System	15 Sep 2020 23:32:16
User entered '15 Sep 2020 18:32'	System	15 Sep 2020 23:32:16

US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:03:01', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bf1a6dd4-0f07-47a6-a4be-b43461fe9a63'	System	09 Sep 2020 21:03:38
User entered 'None (0)'	System	09 Sep 2020 21:03:38

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:03:06', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bf1a6dd4-0f07-47a6-a4be-b43461fe9a63'	System	09 Sep 2020 21:03:38
User entered 'None (0)'	System	09 Sep 2020 21:03:38

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:03:09', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bf1a6dd4-0f07-47a6-a4be-b43461fe9a63'	System	09 Sep 2020 21:03:38
User entered 'None (0)'	System	09 Sep 2020 21:03:38

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:03:13', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bf1a6dd4-0f07-47a6-a4be-b43461fe9a63'	System	09 Sep 2020 21:03:38
User entered 'None (0)'	System	09 Sep 2020 21:03:38

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:03:16', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bf1a6dd4-0f07-47a6-a4be-b43461fe9a63'	System	09 Sep 2020 21:03:38
User entered 'None (0)'	System	09 Sep 2020 21:03:38

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:03:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bf1a6dd4-0f07-47a6-a4be-b43461fe9a63'	System	09 Sep 2020 21:03:38
User entered 'None (0)'	System	09 Sep 2020 21:03:38



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:03:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bf1a6dd4-0f07-47a6-a4be-b43461fe9a63'	System	09 Sep 2020 21:03:38
User entered 'No (N)'	System	09 Sep 2020 21:03:38

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-09T16:03:35', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bf1a6dd4-0f07-47a6-a4be-b43461fe9a63'	System	09 Sep 2020 21:03:38
User entered '09 Sep 2020 16:03'	System	09 Sep 2020 21:03:38

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '09 Sep 2020 15:53'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '09 Sep 2020 18:23'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4c29c7b1-d674-4441-b5d7-30c0474342a5'	System	10 Sep 2020 11:30:55
User entered 'None (0)'	System	10 Sep 2020 11:30:55

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4c29c7b1-d674-4441-b5d7-30c0474342a5'	System	10 Sep 2020 11:30:55
User entered 'None (0)'	System	10 Sep 2020 11:30:55

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:27', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4c29c7b1-d674-4441-b5d7-30c0474342a5'	System	10 Sep 2020 11:30:55
User entered 'None (0)'	System	10 Sep 2020 11:30:55



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4c29c7b1-d674-4441-b5d7-30c0474342a5'	System	10 Sep 2020 11:30:55
User entered 'None (0)'	System	10 Sep 2020 11:30:55

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4c29c7b1-d674-4441-b5d7-30c0474342a5'	System	10 Sep 2020 11:30:55
User entered 'None (0)'	System	10 Sep 2020 11:30:55

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:36', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4c29c7b1-d674-4441-b5d7-30c0474342a5'	System	10 Sep 2020 11:30:55
User entered 'None (0)'	System	10 Sep 2020 11:30:55

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:42', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4c29c7b1-d674-4441-b5d7-30c0474342a5'	System	10 Sep 2020 11:30:55
User entered 'No (N)'	System	10 Sep 2020 11:30:55

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-10T06:30:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4c29c7b1-d674-4441-b5d7-30c0474342a5'	System	10 Sep 2020 11:30:55
User entered '10 Sep 2020 06:30'	System	10 Sep 2020 11:30:55

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '09 Sep 2020 19:18'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 2'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:02:23', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a0741ad3-4597-4ec3-92c1-dc7d37fd3122'	System	11 Sep 2020 11:02:57
User entered 'None (0)'	System	11 Sep 2020 11:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:02:26', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a0741ad3-4597-4ec3-92c1-dc7d37fd3122'	System	11 Sep 2020 11:02:57
User entered 'None (0)'	System	11 Sep 2020 11:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:02:29', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a0741ad3-4597-4ec3-92c1-dc7d37fd3122'	System	11 Sep 2020 11:02:57
User entered 'None (0)'	System	11 Sep 2020 11:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:02:31', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a0741ad3-4597-4ec3-92c1-dc7d37fd3122'	System	11 Sep 2020 11:02:57
User entered 'None (0)'	System	11 Sep 2020 11:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:02:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a0741ad3-4597-4ec3-92c1-dc7d37fd3122'	System	11 Sep 2020 11:02:57
User entered 'None (0)'	System	11 Sep 2020 11:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:02:37', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a0741ad3-4597-4ec3-92c1-dc7d37fd3122'	System	11 Sep 2020 11:02:57
User entered 'None (0)'	System	11 Sep 2020 11:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:02:41', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a0741ad3-4597-4ec3-92c1-dc7d37fd3122'	System	11 Sep 2020 11:02:57
User entered 'No (N)'	System	11 Sep 2020 11:02:57

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T06:02:51', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a0741ad3-4597-4ec3-92c1-dc7d37fd3122'	System	11 Sep 2020 11:02:57
User entered '11 Sep 2020 06:02'	System	11 Sep 2020 11:02:57



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 3'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:23', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a4be375a-2e97-4216-a711-ce85a9eb9ce4'	System	11 Sep 2020 23:04:48
User entered 'None (0)'	System	11 Sep 2020 23:04:48

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:26', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a4be375a-2e97-4216-a711-ce85a9eb9ce4'	System	11 Sep 2020 23:04:48
User entered 'None (0)'	System	11 Sep 2020 23:04:48

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:29', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a4be375a-2e97-4216-a711-ce85a9eb9ce4'	System	11 Sep 2020 23:04:48
User entered 'None (0)'	System	11 Sep 2020 23:04:48

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:31', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a4be375a-2e97-4216-a711-ce85a9eb9ce4'	System	11 Sep 2020 23:04:48
User entered 'None (0)'	System	11 Sep 2020 23:04:48

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a4be375a-2e97-4216-a711-ce85a9eb9ce4'	System	11 Sep 2020 23:04:48
User entered 'None (0)'	System	11 Sep 2020 23:04:48



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:36', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a4be375a-2e97-4216-a711-ce85a9eb9ce4'	System	11 Sep 2020 23:04:48
User entered 'None (0)'	System	11 Sep 2020 23:04:48

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:39', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a4be375a-2e97-4216-a711-ce85a9eb9ce4'	System	11 Sep 2020 23:04:48
User entered 'No (N)'	System	11 Sep 2020 23:04:48

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-11T18:04:45', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'a4be375a-2e97-4216-a711-ce85a9eb9ce4'	System	11 Sep 2020 23:04:48
User entered '11 Sep 2020 18:04'	System	11 Sep 2020 23:04:48

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 4'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:38', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e9ef2396-8460-44f8-a64b-b8636a1b18c2'	System	12 Sep 2020 17:03:33
User entered 'None (0)'	System	12 Sep 2020 17:03:33

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:41', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e9ef2396-8460-44f8-a64b-b8636a1b18c2'	System	12 Sep 2020 17:03:33
User entered 'None (0)'	System	12 Sep 2020 17:03:33



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:43', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e9ef2396-8460-44f8-a64b-b8636a1b18c2'	System	12 Sep 2020 17:03:33
User entered 'None (0)'	System	12 Sep 2020 17:03:33

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:45', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e9ef2396-8460-44f8-a64b-b8636a1b18c2'	System	12 Sep 2020 17:03:33
User entered 'None (0)'	System	12 Sep 2020 17:03:33

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:47', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e9ef2396-8460-44f8-a64b-b8636a1b18c2'	System	12 Sep 2020 17:03:33
User entered 'None (0)'	System	12 Sep 2020 17:03:33

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:49', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e9ef2396-8460-44f8-a64b-b8636a1b18c2'	System	12 Sep 2020 17:03:33
User entered 'None (0)'	System	12 Sep 2020 17:03:33

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:02:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e9ef2396-8460-44f8-a64b-b8636a1b18c2'	System	12 Sep 2020 17:03:33
User entered 'No (N)'	System	12 Sep 2020 17:03:33

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-12T12:03:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e9ef2396-8460-44f8-a64b-b8636a1b18c2'	System	12 Sep 2020 17:03:33
User entered '12 Sep 2020 12:03'	System	12 Sep 2020 17:03:33

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 5'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:41', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7e418ca9-f66f-468e-98bf-ed1e1983723a' User entered 'None (0)'	System	13 Sep 2020 22:54:27
	System	13 Sep 2020 22:54:27

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:45', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7e418ca9-f66f-468e-98bf-ed1e1983723a'	System	13 Sep 2020 22:54:27
User entered 'None (0)'	System	13 Sep 2020 22:54:27

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:47', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7e418ca9-f66f-468e-98bf-ed1e1983723a'	System	13 Sep 2020 22:54:27
User entered 'None (0)'	System	13 Sep 2020 22:54:27

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:53', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7e418ca9-f66f-468e-98bf-ed1e1983723a' User entered 'None (0)'	System	13 Sep 2020 22:54:27
	System	13 Sep 2020 22:54:27

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:55', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7e418ca9-f66f-468e-98bf-ed1e1983723a'	System	13 Sep 2020 22:54:27
User entered 'None (0)'	System	13 Sep 2020 22:54:27

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:57', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7e418ca9-f66f-468e-98bf-ed1e1983723a'	System	13 Sep 2020 22:54:27
User entered 'None (0)'	System	13 Sep 2020 22:54:27

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:53:59', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7e418ca9-f66f-468e-98bf-ed1e1983723a'	System	13 Sep 2020 22:54:27
User entered 'No (N)'	System	13 Sep 2020 22:54:27



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-13T17:54:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7e418ca9-f66f-468e-98bf-ed1e1983723a'	System	13 Sep 2020 22:54:27
User entered '13 Sep 2020 17:54'	System	13 Sep 2020 22:54:27

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 6'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:40', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5b080c9f-6174-42b1-8a38-1484d5c8da3e'	System	15 Sep 2020 11:28:02
User entered 'None (0)'	System	15 Sep 2020 11:28:02

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:42', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5b080c9f-6174-42b1-8a38-1484d5c8da3e'	System	15 Sep 2020 11:28:02
User entered 'None (0)'	System	15 Sep 2020 11:28:02

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:44', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5b080c9f-6174-42b1-8a38-1484d5c8da3e'	System	15 Sep 2020 11:28:02
User entered 'None (0)'	System	15 Sep 2020 11:28:02

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:45', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5b080c9f-6174-42b1-8a38-1484d5c8da3e'	System	15 Sep 2020 11:28:02
User entered 'None (0)'	System	15 Sep 2020 11:28:02



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:47', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5b080c9f-6174-42b1-8a38-1484d5c8da3e'	System	15 Sep 2020 11:28:02
User entered 'None (0)'	System	15 Sep 2020 11:28:02

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:49', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5b080c9f-6174-42b1-8a38-1484d5c8da3e'	System	15 Sep 2020 11:28:02
User entered 'None (0)'	System	15 Sep 2020 11:28:02

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5b080c9f-6174-42b1-8a38-1484d5c8da3e'	System	15 Sep 2020 11:28:02
User entered 'No (N)'	System	15 Sep 2020 11:28:02

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T06:27:58', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5b080c9f-6174-42b1-8a38-1484d5c8da3e'	System	15 Sep 2020 11:28:02
User entered '15 Sep 2020 06:27'	System	15 Sep 2020 11:28:02

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 7'	System	09 Sep 2020 20:50:36

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:17', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2774ef66-ed48-4cf0-b43e-5aab6933f6f8'	System	15 Sep 2020 23:32:43
User entered 'None (0)'	System	15 Sep 2020 23:32:43



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:20', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2774ef66-ed48-4cf0-b43e-5aab6933f6f8'	System	15 Sep 2020 23:32:43
User entered 'None (0)'	System	15 Sep 2020 23:32:43

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:22', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2774ef66-ed48-4cf0-b43e-5aab6933f6f8'	System	15 Sep 2020 23:32:43
User entered 'None (0)'	System	15 Sep 2020 23:32:43

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2774ef66-ed48-4cf0-b43e-5aab6933f6f8'	System	15 Sep 2020 23:32:43
User entered 'None (0)'	System	15 Sep 2020 23:32:43

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:26', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2774ef66-ed48-4cf0-b43e-5aab6933f6f8'	System	15 Sep 2020 23:32:43
User entered 'None (0)'	System	15 Sep 2020 23:32:43

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:28', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2774ef66-ed48-4cf0-b43e-5aab6933f6f8'	System	15 Sep 2020 23:32:43
User entered 'None (0)'	System	15 Sep 2020 23:32:43

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2774ef66-ed48-4cf0-b43e-5aab6933f6f8'	System	15 Sep 2020 23:32:43
User entered 'No (N)'	System	15 Sep 2020 23:32:43

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-09-15T18:32:39', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2774ef66-ed48-4cf0-b43e-5aab6933f6f8'	System	15 Sep 2020 23:32:43
User entered '15 Sep 2020 18:32'	System	15 Sep 2020 23:32:43

US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 20:50:36



US3552386

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Joan Siegner (b) (4)	16 Sep 2020 18:24:33

US3552386

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '16 Sep 2020'	(b) (4) Joan Siegner (b) (4)	16 Sep 2020 18:24:33

US3552386

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Joan Siegner (b) (4)	16 Sep 2020 18:24:33

US3552386

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Joan Siegner (b) (4) [REDACTED]	16 Sep 2020 18:24:33

US3552386

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 19:10:10

US3552386

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'l'	System	23 Sep 2020 19:10:10

US3552386

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 19:10:33



US3552386

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '23 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 19:10:33

US3552386

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 19:10:33

US3552386

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 19:10:33

US3552386

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:39:40

US3552386

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'I'	System	30 Sep 2020 17:39:40

US3552386

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:39:49

US3552386

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '30 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:39:49

US3552386

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:39:49



US3552386

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:39:49

US3552386

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:13:24

US3552386

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'I'	System	13 Oct 2020 20:13:24

US3552386

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:33

US3552386

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '13 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:33

US3552386

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[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 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:33

**US3552386**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'VISIT2'	System	14 Oct 2020 12:22:33

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 12:22:54



US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '13 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '14:55'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '13 Oct 2020 14:55'	System	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '98.7' F	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '74'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54



US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'bpm'	System	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '14'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'breaths/min'	System	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '132'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'mmHg'	System	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '81'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'mmHg'	System	14 Oct 2020 12:22:54

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 12:23:20



US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '13 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '16:07'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '13 Oct 2020 16:07'	System	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '98.4' F	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '76'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20



US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'bpm'	System	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '16'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'breaths/min'	System	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '123'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'mmHg'	System	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '81'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'mmHg'	System	14 Oct 2020 12:23:20

US3552386

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:28



US3552386

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '13 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:28

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:41:26

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:41:26

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

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 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:41:26

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 20:41:26

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:41:26

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '15:37'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:41:26

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '13 Oct 2020 15:37'	System	13 Oct 2020 20:41:26



US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Oct 2020 20:41:26

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'ONCE'	System	13 Oct 2020 20:41:26

US3552386

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 20:41:26

US3552386

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:40

US3552386

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '13 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:40

US3552386

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered '15:09'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:40

US3552386

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '13 Oct 2020 15:09'	System	14 Oct 2020 12:23:40

US3552386

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '13 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:50



US3552386

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 12:23:50

US3552386

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:50

US3552386

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '15:11'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:50

**US3552386**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '13 Oct 2020 15:11'	System	14 Oct 2020 12:23:50

US3552386

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Doublin (b) (4) (b) (4)	14 Oct 2020 12:23:50

US3552386

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:50

US3552386

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Oct 2020 12:23:50

**US3552386**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered empty.	System	14 Oct 2020 12:23:50



US3552386

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Oct 2020 21:40:13

US3552386

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'I'	System	20 Oct 2020 21:40:13

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:06:27', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '08a5dab3-8649-4063-8ab6-28cf38a094be'	System	13 Oct 2020 21:06:46
User entered 'Yes (Y)'	System	13 Oct 2020 21:06:46

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:06:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '08a5dab3-8649-4063-8ab6-28cf38a094be'	System	13 Oct 2020 21:06:46
User entered '98.4'	System	13 Oct 2020 21:06:46

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:06:37', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '08a5dab3-8649-4063-8ab6-28cf38a094be'	System	13 Oct 2020 21:06:46
User entered 'No (N)'	System	13 Oct 2020 21:06:46

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:06:44', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '08a5dab3-8649-4063-8ab6-28cf38a094be'	System	13 Oct 2020 21:06:46
User entered '13 Oct 2020 16:06'	System	13 Oct 2020 21:06:46

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Oct 2020 15:57'	System	13 Oct 2020 20:41:26



US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Oct 2020 18:27'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:11:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ce93f18c-fd52-4f6d-bb2f-b6436bee3d9a'	System	14 Oct 2020 10:11:58
User entered 'Yes (Y)'	System	14 Oct 2020 10:11:58

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:11:44', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ce93f18c-fd52-4f6d-bb2f-b6436bee3d9a'	System	14 Oct 2020 10:11:58
User entered '98.7'	System	14 Oct 2020 10:11:58

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:11:47', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ce93f18c-fd52-4f6d-bb2f-b6436bee3d9a'	System	14 Oct 2020 10:11:58
User entered 'No (N)'	System	14 Oct 2020 10:11:58

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:11:53', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ce93f18c-fd52-4f6d-bb2f-b6436bee3d9a'	System	14 Oct 2020 10:11:58
User entered '14 Oct 2020 05:11'	System	14 Oct 2020 10:11:58

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Oct 2020 19:22'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 20:41:26



US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 2'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:00:45', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '9d158f39-c440-458d-a793-0d8d55c49675'	System	15 Oct 2020 05:01:06
User entered 'Yes (Y)'	System	15 Oct 2020 05:01:06

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:00:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '9d158f39-c440-458d-a793-0d8d55c49675'	System	15 Oct 2020 05:01:06
User entered '98.3'	System	15 Oct 2020 05:01:06

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:00:55', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '9d158f39-c440-458d-a793-0d8d55c49675'	System	15 Oct 2020 05:01:06
User entered 'No (N)'	System	15 Oct 2020 05:01:06

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:00:59', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '9d158f39-c440-458d-a793-0d8d55c49675'	System	15 Oct 2020 05:01:06
User entered '15 Oct 2020 00:00'	System	15 Oct 2020 05:01:06

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 3'	System	13 Oct 2020 20:41:26



US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:04', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '851a82e5-215e-4ab6-b358-cca19143ead7'	System	15 Oct 2020 17:15:36
User entered 'Yes (Y)'	System	15 Oct 2020 17:15:36

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:15', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '851a82e5-215e-4ab6-b358-cca19143ead7'	System	15 Oct 2020 17:15:36
User entered '98.6'	System	15 Oct 2020 17:15:36

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:23', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '851a82e5-215e-4ab6-b358-cca19143ead7'	System	15 Oct 2020 17:15:36
User entered 'No (N)'	System	15 Oct 2020 17:15:36

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '851a82e5-215e-4ab6-b358-cca19143ead7'	System	15 Oct 2020 17:15:36
User entered '15 Oct 2020 12:15'	System	15 Oct 2020 17:15:36

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 4'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:09', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '8513ef97-7705-4480-86ab-aacb623605e3'	System	16 Oct 2020 17:11:27
User entered 'Yes (Y)'	System	16 Oct 2020 17:11:27



US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:17', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '8513ef97-7705-4480-86ab-aacb623605e3' User entered '98.3'	System	16 Oct 2020 17:11:27
	System	16 Oct 2020 17:11:27

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '8513ef97-7705-4480-86ab-aacb623605e3'	System	16 Oct 2020 17:11:27
User entered 'No (N)'	System	16 Oct 2020 17:11:27

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:23', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '8513ef97-7705-4480-86ab-aacb623605e3'	System	16 Oct 2020 17:11:27
User entered '16 Oct 2020 12:11'	System	16 Oct 2020 17:11:27

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 5'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:08', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '08febfea-51da-40cd-8163-7030550473b0'	System	18 Oct 2020 15:22:25
User entered 'Yes (Y)'	System	18 Oct 2020 15:22:25

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:13', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '08febfea-51da-40cd-8163-7030550473b0'	System	18 Oct 2020 15:22:25
User entered '98.5'	System	18 Oct 2020 15:22:25



US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:15', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '08febfea-51da-40cd-8163-7030550473b0'	System	18 Oct 2020 15:22:25
User entered 'No (N)'	System	18 Oct 2020 15:22:25

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:20', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '08febfea-51da-40cd-8163-7030550473b0'	System	18 Oct 2020 15:22:25
User entered '18 Oct 2020 10:22'	System	18 Oct 2020 15:22:25

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 6'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:00:58', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b7b1cc26-a012-4483-9191-f2bf658942d0'	System	18 Oct 2020 17:01:29
User entered 'Yes (Y)'	System	18 Oct 2020 17:01:29

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:12', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b7b1cc26-a012-4483-9191-f2bf658942d0'	System	18 Oct 2020 17:01:29
User entered '98.3'	System	18 Oct 2020 17:01:29

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:15', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b7b1cc26-a012-4483-9191-f2bf658942d0'	System	18 Oct 2020 17:01:29
User entered 'No (N)'	System	18 Oct 2020 17:01:29



US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:20', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b7b1cc26-a012-4483-9191-f2bf658942d0'	System	18 Oct 2020 17:01:29
User entered '18 Oct 2020 12:01'	System	18 Oct 2020 17:01:29

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 7'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:01:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4ea52d79-5eb8-45d5-b675-c4f9729e077c'	System	19 Oct 2020 17:01:54
User entered 'Yes (Y)'	System	19 Oct 2020 17:01:54

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:01:36', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4ea52d79-5eb8-45d5-b675-c4f9729e077c' User entered '98.5'	System	19 Oct 2020 17:01:54
	System	19 Oct 2020 17:01:54

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:01:39', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4ea52d79-5eb8-45d5-b675-c4f9729e077c'	System	19 Oct 2020 17:01:54
User entered 'No (N)'	System	19 Oct 2020 17:01:54

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:01:43', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '4ea52d79-5eb8-45d5-b675-c4f9729e077c'	System	19 Oct 2020 17:01:54
User entered '19 Oct 2020 12:01'	System	19 Oct 2020 17:01:54



US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2ea8778-bbf3-4899-b77e-672bd3c71787'	System	13 Oct 2020 21:07:30
User entered 'None (1)'	System	13 Oct 2020 21:07:30

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:14', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2ea8778-bbf3-4899-b77e-672bd3c71787'	System	13 Oct 2020 21:07:30
User entered 'No (N)'	System	13 Oct 2020 21:07:30

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:17', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2ea8778-bbf3-4899-b77e-672bd3c71787'	System	13 Oct 2020 21:07:30
User entered 'No (N)'	System	13 Oct 2020 21:07:30

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:21', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2ea8778-bbf3-4899-b77e-672bd3c71787'	System	13 Oct 2020 21:07:30
User entered 'None (1)'	System	13 Oct 2020 21:07:30

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:28', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2ea8778-bbf3-4899-b77e-672bd3c71787'	System	13 Oct 2020 21:07:30
User entered '13 Oct 2020 16:07'	System	13 Oct 2020 21:07:30



US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Oct 2020 15:57'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Oct 2020 18:27'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:11:59', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b5fd5f0d-eeed-4e54-bcf2-1bacc411f874'	System	14 Oct 2020 10:12:30
User entered 'None (1)'	System	14 Oct 2020 10:12:30

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:09', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b5fd5f0d-eeed-4e54-bcf2-1bacc411f874'	System	14 Oct 2020 10:12:30
User entered 'No (N)'	System	14 Oct 2020 10:12:30

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:13', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b5fd5f0d-eeed-4e54-bcf2-1bacc411f874'	System	14 Oct 2020 10:12:30
User entered 'No (N)'	System	14 Oct 2020 10:12:30

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:17', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b5fd5f0d-eeed-4e54-bcf2-1bacc411f874'	System	14 Oct 2020 10:12:30
User entered 'None (1)'	System	14 Oct 2020 10:12:30

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:26', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b5fd5f0d-eeed-4e54-bcf2-1bacc411f874'	System	14 Oct 2020 10:12:30
User entered '14 Oct 2020 05:12'	System	14 Oct 2020 10:12:30



US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Oct 2020 19:22'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 2'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:10', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6c0d4c57-e55c-4cab-a07d-64c0e1de037d'	System	15 Oct 2020 05:01:31
User entered 'None (1)'	System	15 Oct 2020 05:01:31

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:13', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6c0d4c57-e55c-4cab-a07d-64c0e1de037d'	System	15 Oct 2020 05:01:31
User entered 'No (N)'	System	15 Oct 2020 05:01:31

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:16', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6c0d4c57-e55c-4cab-a07d-64c0e1de037d'	System	15 Oct 2020 05:01:31
User entered 'No (N)'	System	15 Oct 2020 05:01:31

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6c0d4c57-e55c-4cab-a07d-64c0e1de037d'	System	15 Oct 2020 05:01:31
User entered 'None (1)'	System	15 Oct 2020 05:01:31

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:27', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6c0d4c57-e55c-4cab-a07d-64c0e1de037d'	System	15 Oct 2020 05:01:31
User entered '15 Oct 2020 00:01'	System	15 Oct 2020 05:01:31



US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 3'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:37', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b3591726-7c95-4b6a-ab5c-6a74586eb1d9'	System	15 Oct 2020 17:15:56
User entered 'None (1)'	System	15 Oct 2020 17:15:56

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:39', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b3591726-7c95-4b6a-ab5c-6a74586eb1d9'	System	15 Oct 2020 17:15:56
User entered 'No (N)'	System	15 Oct 2020 17:15:56

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:42', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b3591726-7c95-4b6a-ab5c-6a74586eb1d9'	System	15 Oct 2020 17:15:56
User entered 'No (N)'	System	15 Oct 2020 17:15:56

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:44', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b3591726-7c95-4b6a-ab5c-6a74586eb1d9'	System	15 Oct 2020 17:15:56
User entered 'None (1)'	System	15 Oct 2020 17:15:56

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b3591726-7c95-4b6a-ab5c-6a74586eb1d9'	System	15 Oct 2020 17:15:56
User entered '15 Oct 2020 12:15'	System	15 Oct 2020 17:15:56



US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 4'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:28', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04070278-4fc4-488f-ae14-fc5a158b057f'	System	16 Oct 2020 17:11:48
User entered 'None (1)'	System	16 Oct 2020 17:11:48

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04070278-4fc4-488f-ae14-fc5a158b057f'	System	16 Oct 2020 17:11:48
User entered 'No (N)'	System	16 Oct 2020 17:11:48

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04070278-4fc4-488f-ae14-fc5a158b057f'	System	16 Oct 2020 17:11:48
User entered 'No (N)'	System	16 Oct 2020 17:11:48

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:35', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04070278-4fc4-488f-ae14-fc5a158b057f'	System	16 Oct 2020 17:11:48
User entered 'None (1)'	System	16 Oct 2020 17:11:48

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:42', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04070278-4fc4-488f-ae14-fc5a158b057f'	System	16 Oct 2020 17:11:48
User entered '16 Oct 2020 12:11'	System	16 Oct 2020 17:11:48



US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 5'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2349f2f5-dcef-4b71-93fd-e6e0d3a9090f'	System	18 Oct 2020 15:22:43
User entered 'None (1)'	System	18 Oct 2020 15:22:43

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:27', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2349f2f5-dcef-4b71-93fd-e6e0d3a9090f'	System	18 Oct 2020 15:22:43
User entered 'No (N)'	System	18 Oct 2020 15:22:43

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:29', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2349f2f5-dcef-4b71-93fd-e6e0d3a9090f'	System	18 Oct 2020 15:22:43
User entered 'No (N)'	System	18 Oct 2020 15:22:43

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2349f2f5-dcef-4b71-93fd-e6e0d3a9090f'	System	18 Oct 2020 15:22:43
User entered 'None (1)'	System	18 Oct 2020 15:22:43

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:39', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2349f2f5-dcef-4b71-93fd-e6e0d3a9090f' User entered '18 Oct 2020 10:22'	System	18 Oct 2020 15:22:43
	System	18 Oct 2020 15:22:43



US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 6'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:26', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '29a686b0-a019-4746-93ee-fb3fe238177f'	System	18 Oct 2020 17:01:42
User entered 'None (1)'	System	18 Oct 2020 17:01:42

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:28', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '29a686b0-a019-4746-93ee-fb3fe238177f'	System	18 Oct 2020 17:01:42
User entered 'No (N)'	System	18 Oct 2020 17:01:42

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '29a686b0-a019-4746-93ee-fb3fe238177f'	System	18 Oct 2020 17:01:42
User entered 'No (N)'	System	18 Oct 2020 17:01:42

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:31', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '29a686b0-a019-4746-93ee-fb3fe238177f'	System	18 Oct 2020 17:01:42
User entered 'None (1)'	System	18 Oct 2020 17:01:42

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:37', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '29a686b0-a019-4746-93ee-fb3fe238177f'	System	18 Oct 2020 17:01:42
User entered '18 Oct 2020 12:01'	System	18 Oct 2020 17:01:42



US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 7'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:01:48', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2479928-33e8-4ea8-bd6f-ce77edc331c1'	System	19 Oct 2020 17:02:07
User entered 'None (1)'	System	19 Oct 2020 17:02:07

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:01:50', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2479928-33e8-4ea8-bd6f-ce77edc331c1'	System	19 Oct 2020 17:02:07
User entered 'No (N)'	System	19 Oct 2020 17:02:07

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:01:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2479928-33e8-4ea8-bd6f-ce77edc331c1'	System	19 Oct 2020 17:02:07
User entered 'No (N)'	System	19 Oct 2020 17:02:07

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:01:54', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2479928-33e8-4ea8-bd6f-ce77edc331c1'	System	19 Oct 2020 17:02:07
User entered 'None (1)'	System	19 Oct 2020 17:02:07

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:02:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'e2479928-33e8-4ea8-bd6f-ce77edc331c1'	System	19 Oct 2020 17:02:07
User entered '19 Oct 2020 12:02'	System	19 Oct 2020 17:02:07



US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '077f9163-53ec-4a19-920e-ca83bba02ed5'	System	13 Oct 2020 21:08:08
User entered 'None (0)'	System	13 Oct 2020 21:08:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:38', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '077f9163-53ec-4a19-920e-ca83bba02ed5'	System	13 Oct 2020 21:08:08
User entered 'None (0)'	System	13 Oct 2020 21:08:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:41', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '077f9163-53ec-4a19-920e-ca83bba02ed5'	System	13 Oct 2020 21:08:08
User entered 'None (0)'	System	13 Oct 2020 21:08:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:44', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '077f9163-53ec-4a19-920e-ca83bba02ed5'	System	13 Oct 2020 21:08:08
User entered 'None (0)'	System	13 Oct 2020 21:08:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:48', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '077f9163-53ec-4a19-920e-ca83bba02ed5'	System	13 Oct 2020 21:08:08
User entered 'None (0)'	System	13 Oct 2020 21:08:08



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:51', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '077f9163-53ec-4a19-920e-ca83bba02ed5'	System	13 Oct 2020 21:08:08
User entered 'None (0)'	System	13 Oct 2020 21:08:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:07:54', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '077f9163-53ec-4a19-920e-ca83bba02ed5'	System	13 Oct 2020 21:08:08
User entered 'No (N)'	System	13 Oct 2020 21:08:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-13T16:08:03', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '077f9163-53ec-4a19-920e-ca83bba02ed5'	System	13 Oct 2020 21:08:08
User entered '13 Oct 2020 16:08'	System	13 Oct 2020 21:08:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Oct 2020 15:57'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Oct 2020 18:27'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6359fc6d-4d5c-4a19-b4bc-140d92fa491f'	System	14 Oct 2020 10:13:02
User entered 'None (0)'	System	14 Oct 2020 10:13:02

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:33', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6359fc6d-4d5c-4a19-b4bc-140d92fa491f'	System	14 Oct 2020 10:13:02
User entered 'None (0)'	System	14 Oct 2020 10:13:02



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:37', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6359fc6d-4d5c-4a19-b4bc-140d92fa491f'	System	14 Oct 2020 10:13:02
User entered 'None (0)'	System	14 Oct 2020 10:13:02

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:40', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6359fc6d-4d5c-4a19-b4bc-140d92fa491f'	System	14 Oct 2020 10:13:02
User entered 'None (0)'	System	14 Oct 2020 10:13:02

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:42', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6359fc6d-4d5c-4a19-b4bc-140d92fa491f'	System	14 Oct 2020 10:13:02
User entered 'None (0)'	System	14 Oct 2020 10:13:02

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:44', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6359fc6d-4d5c-4a19-b4bc-140d92fa491f'	System	14 Oct 2020 10:13:02
User entered 'None (0)'	System	14 Oct 2020 10:13:02

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:47', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6359fc6d-4d5c-4a19-b4bc-140d92fa491f'	System	14 Oct 2020 10:13:02
User entered 'No (N)'	System	14 Oct 2020 10:13:02

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-14T05:12:57', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6359fc6d-4d5c-4a19-b4bc-140d92fa491f'	System	14 Oct 2020 10:13:02
User entered '14 Oct 2020 05:12'	System	14 Oct 2020 10:13:02

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '13 Oct 2020 19:22'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 20:41:26



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 2'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c9916c8a-6531-425d-97d4-5514dfd9028b'	System	15 Oct 2020 05:01:59
User entered 'None (0)'	System	15 Oct 2020 05:01:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c9916c8a-6531-425d-97d4-5514dfd9028b'	System	15 Oct 2020 05:01:59
User entered 'None (0)'	System	15 Oct 2020 05:01:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:36', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c9916c8a-6531-425d-97d4-5514dfd9028b'	System	15 Oct 2020 05:01:59
User entered 'None (0)'	System	15 Oct 2020 05:01:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:38', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c9916c8a-6531-425d-97d4-5514dfd9028b'	System	15 Oct 2020 05:01:59
User entered 'None (0)'	System	15 Oct 2020 05:01:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:40', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c9916c8a-6531-425d-97d4-5514dfd9028b'	System	15 Oct 2020 05:01:59
User entered 'None (0)'	System	15 Oct 2020 05:01:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:42', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c9916c8a-6531-425d-97d4-5514dfd9028b'	System	15 Oct 2020 05:01:59
User entered 'None (0)'	System	15 Oct 2020 05:01:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:45', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c9916c8a-6531-425d-97d4-5514dfd9028b'	System	15 Oct 2020 05:01:59
User entered 'No (N)'	System	15 Oct 2020 05:01:59



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T00:01:55', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c9916c8a-6531-425d-97d4-5514dfd9028b'	System	15 Oct 2020 05:01:59
User entered '15 Oct 2020 00:01'	System	15 Oct 2020 05:01:59

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

**US3552386**

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

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

**Generated On: 10 Jun 2021 08:16:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 3'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:15:57', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49d40d02-2c6c-410a-a63a-e9cc32d72f16'	System	15 Oct 2020 17:16:27
User entered 'None (0)'	System	15 Oct 2020 17:16:27

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:16:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49d40d02-2c6c-410a-a63a-e9cc32d72f16'	System	15 Oct 2020 17:16:27
User entered 'None (0)'	System	15 Oct 2020 17:16:27

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:16:03', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49d40d02-2c6c-410a-a63a-e9cc32d72f16'	System	15 Oct 2020 17:16:27
User entered 'None (0)'	System	15 Oct 2020 17:16:27

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:16:05', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49d40d02-2c6c-410a-a63a-e9cc32d72f16'	System	15 Oct 2020 17:16:27
User entered 'None (0)'	System	15 Oct 2020 17:16:27



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:16:07', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49d40d02-2c6c-410a-a63a-e9cc32d72f16'	System	15 Oct 2020 17:16:27
User entered 'None (0)'	System	15 Oct 2020 17:16:27

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:16:09', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49d40d02-2c6c-410a-a63a-e9cc32d72f16'	System	15 Oct 2020 17:16:27
User entered 'None (0)'	System	15 Oct 2020 17:16:27

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:16:12', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49d40d02-2c6c-410a-a63a-e9cc32d72f16'	System	15 Oct 2020 17:16:27
User entered 'No (N)'	System	15 Oct 2020 17:16:27

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-15T12:16:20', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49d40d02-2c6c-410a-a63a-e9cc32d72f16'	System	15 Oct 2020 17:16:27
User entered '15 Oct 2020 12:16'	System	15 Oct 2020 17:16:27

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 4'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:46', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1520288a-4c97-4849-822f-5fa8a349c9f5'	System	16 Oct 2020 17:12:11
User entered 'None (0)'	System	16 Oct 2020 17:12:11



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:48', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1520288a-4c97-4849-822f-5fa8a349c9f5'	System	16 Oct 2020 17:12:11
User entered 'None (0)'	System	16 Oct 2020 17:12:11

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:50', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1520288a-4c97-4849-822f-5fa8a349c9f5'	System	16 Oct 2020 17:12:11
User entered 'None (0)'	System	16 Oct 2020 17:12:11

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1520288a-4c97-4849-822f-5fa8a349c9f5'	System	16 Oct 2020 17:12:11
User entered 'None (0)'	System	16 Oct 2020 17:12:11

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:54', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1520288a-4c97-4849-822f-5fa8a349c9f5'	System	16 Oct 2020 17:12:11
User entered 'None (0)'	System	16 Oct 2020 17:12:11

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:11:57', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1520288a-4c97-4849-822f-5fa8a349c9f5'	System	16 Oct 2020 17:12:11
User entered 'None (0)'	System	16 Oct 2020 17:12:11

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:12:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1520288a-4c97-4849-822f-5fa8a349c9f5'	System	16 Oct 2020 17:12:11
User entered 'No (N)'	System	16 Oct 2020 17:12:11

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-16T12:12:08', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1520288a-4c97-4849-822f-5fa8a349c9f5'	System	16 Oct 2020 17:12:11
User entered '16 Oct 2020 12:12'	System	16 Oct 2020 17:12:11

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 20:41:26



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 5'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:49', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c67c8436-c74c-4129-b2df-9951c29b1570'	System	18 Oct 2020 15:23:14
User entered 'None (0)'	System	18 Oct 2020 15:23:14

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c67c8436-c74c-4129-b2df-9951c29b1570'	System	18 Oct 2020 15:23:14
User entered 'None (0)'	System	18 Oct 2020 15:23:14

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:54', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c67c8436-c74c-4129-b2df-9951c29b1570'	System	18 Oct 2020 15:23:14
User entered 'None (0)'	System	18 Oct 2020 15:23:14

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:55', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c67c8436-c74c-4129-b2df-9951c29b1570'	System	18 Oct 2020 15:23:14
User entered 'None (0)'	System	18 Oct 2020 15:23:14

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:57', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c67c8436-c74c-4129-b2df-9951c29b1570'	System	18 Oct 2020 15:23:14
User entered 'None (0)'	System	18 Oct 2020 15:23:14

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:22:59', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c67c8436-c74c-4129-b2df-9951c29b1570'	System	18 Oct 2020 15:23:14
User entered 'None (0)'	System	18 Oct 2020 15:23:14



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:23:02', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c67c8436-c74c-4129-b2df-9951c29b1570'	System	18 Oct 2020 15:23:14
User entered 'No (N)'	System	18 Oct 2020 15:23:14

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T10:23:09', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c67c8436-c74c-4129-b2df-9951c29b1570'	System	18 Oct 2020 15:23:14
User entered '18 Oct 2020 10:23'	System	18 Oct 2020 15:23:14

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 6'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:43', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ffd52475-a5bb-4612-ba14-e96091813b6b'	System	18 Oct 2020 17:02:08
User entered 'None (0)'	System	18 Oct 2020 17:02:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:44', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ffd52475-a5bb-4612-ba14-e96091813b6b'	System	18 Oct 2020 17:02:08
User entered 'None (0)'	System	18 Oct 2020 17:02:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:46', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ffd52475-a5bb-4612-ba14-e96091813b6b'	System	18 Oct 2020 17:02:08
User entered 'None (0)'	System	18 Oct 2020 17:02:08



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:48', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ffd52475-a5bb-4612-ba14-e96091813b6b'	System	18 Oct 2020 17:02:08
User entered 'None (0)'	System	18 Oct 2020 17:02:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:50', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ffd52475-a5bb-4612-ba14-e96091813b6b' User entered 'None (0)'	System	18 Oct 2020 17:02:08
	System	18 Oct 2020 17:02:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:52', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ffd52475-a5bb-4612-ba14-e96091813b6b'	System	18 Oct 2020 17:02:08
User entered 'None (0)'	System	18 Oct 2020 17:02:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:01:53', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ffd52475-a5bb-4612-ba14-e96091813b6b'	System	18 Oct 2020 17:02:08
User entered 'No (N)'	System	18 Oct 2020 17:02:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-18T12:02:01', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'ffd52475-a5bb-4612-ba14-e96091813b6b'	System	18 Oct 2020 17:02:08
User entered '18 Oct 2020 12:02'	System	18 Oct 2020 17:02:08

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:16:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	13 Oct 2020 20:41:26
User entered 'Day 7'	System	13 Oct 2020 20:41:26



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:02:09', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fe55a85a-3076-4c50-87e3-051f6737f392'	System	19 Oct 2020 17:02:41
User entered 'None (0)'	System	19 Oct 2020 17:02:41

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:02:12', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fe55a85a-3076-4c50-87e3-051f6737f392'	System	19 Oct 2020 17:02:41
User entered 'None (0)'	System	19 Oct 2020 17:02:41

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:02:15', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fe55a85a-3076-4c50-87e3-051f6737f392'	System	19 Oct 2020 17:02:41
User entered 'None (0)'	System	19 Oct 2020 17:02:41

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:02:17', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fe55a85a-3076-4c50-87e3-051f6737f392'	System	19 Oct 2020 17:02:41
User entered 'None (0)'	System	19 Oct 2020 17:02:41

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:02:18', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fe55a85a-3076-4c50-87e3-051f6737f392'	System	19 Oct 2020 17:02:41
User entered 'None (0)'	System	19 Oct 2020 17:02:41

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:02:20', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fe55a85a-3076-4c50-87e3-051f6737f392'	System	19 Oct 2020 17:02:41
User entered 'None (0)'	System	19 Oct 2020 17:02:41

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:02:23', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fe55a85a-3076-4c50-87e3-051f6737f392'	System	19 Oct 2020 17:02:41
User entered 'No (N)'	System	19 Oct 2020 17:02:41

US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-10-19T12:02:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fe55a85a-3076-4c50-87e3-051f6737f392'	System	19 Oct 2020 17:02:41
User entered '19 Oct 2020 12:02'	System	19 Oct 2020 17:02:41



US3552386

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:16:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 20:41:26

**US3552386**

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

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

**Generated On: 10 Jun 2021 08:16:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 20:41:26

US3552386

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	20 Oct 2020 21:40:21

US3552386

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '20 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	20 Oct 2020 21:40:21

US3552386

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	20 Oct 2020 21:40:21

US3552386

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Mikayla Frye (b) (4) (b) (4)	20 Oct 2020 21:40:21

US3552386

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 16:02:48

US3552386

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'l'	System	27 Oct 2020 16:02:48



US3552386

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 16:02:57

US3552386

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '27 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 16:02:57

US3552386

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 16:02:57

US3552386

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 16:02:57

US3552386

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 15:50:05

US3552386

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'I'	System	04 Nov 2020 15:50:05

US3552386

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 15:50:20

US3552386

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 15:52:42
User entered '4 Nov 2020'	(b) (4)	
	Mikayla Frye (b) (4)	04 Nov 2020 15:50:20
	(b) (4)	



US3552386

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 15:50:20

US3552386

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Nov 2020 15:50:20

US3552386

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:06:39

US3552386

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'I'	System	11 Nov 2020 13:06:39

US3552386

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:37

US3552386

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '10 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:37

US3552386

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[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 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:37

**US3552386**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'VISIT3'	System	11 Nov 2020 13:07:37



US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered empty.	(b) (4) Stanley Dublin (b) (4)	11 Nov 2020 13:07:43

**US3552386**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered empty.	System	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:43



**US3552386**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered empty.	System	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered empty.	System	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:43

**US3552386**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered empty.	System	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered empty.	System	11 Nov 2020 13:07:43

US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04



US3552386

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04

US3552386

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:50

US3552386

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered empty.	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:07:50

US3552386

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:08:01

US3552386

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '10 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:08:01

US3552386

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered '15:39'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Nov 2020 13:08:01

US3552386

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered '10 Nov 2020 15:39'	System	11 Nov 2020 13:08:01

US3552386

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:52
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Dec 2020 22:01:17



US3552386

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'I'	System	08 Dec 2020 22:01:17

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 64'	System	09 Sep 2020 20:50:36

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

[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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-11-12T20:13:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '9b113ffa-e0ec-4de5-86d1-551e31bac280'	System	13 Nov 2020 02:13:38
User entered 'No (N)'	System	13 Nov 2020 02:13:38

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

Have you been exposed to someone with 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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-11-12T20:13:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '9b113ffa-e0ec-4de5-86d1-551e31bac280'	System	13 Nov 2020 02:13:38
User entered 'No (N)'	System	13 Nov 2020 02:13:38

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-11-12T20:13:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '9b113ffa-e0ec-4de5-86d1-551e31bac280'	System	13 Nov 2020 02:13:38
User entered '12 Nov 2020 20:13:34'	System	13 Nov 2020 02:13:38

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 20:50:36

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 20:50:36

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered 'Day 71'	System	09 Sep 2020 20:50:36



US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

[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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-11-17T20:05:51', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '129809fa-a82c-481e-a585-6c9cc0a37919'	System	18 Nov 2020 02:06:17
User entered 'No (N)'	System	18 Nov 2020 02:06:17

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

Have you been exposed to someone with 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 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-11-17T20:05:55', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '129809fa-a82c-481e-a585-6c9cc0a37919'	System	18 Nov 2020 02:06:17
User entered 'Yes (Y)'	System	18 Nov 2020 02:06:17

US3552386

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-11-17T20:06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '129809fa-a82c-481e-a585-6c9cc0a37919'	System	18 Nov 2020 02:06:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 02:06:17

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-11-17T20:06:05', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '129809fa-a82c-481e-a585-6c9cc0a37919'	System	18 Nov 2020 02:06:17
User entered '17 Nov 2020 20:06:05'	System	18 Nov 2020 02:06:17

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 20:50:36

US3552386

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:22:02
Data entry locked.	System	09 Sep 2020 20:50:36
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 20:50:36

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2020-11-23T20:24:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '3a67cfd1-4b42-40c2-9449-54e5352b88ea'	System	24 Nov 2020 02:24:31
User entered 'No (N)'	System	24 Nov 2020 02:24:31



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2020-11-23T20:24:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '3a67cfd1-4b42-40c2-9449-54e5352b88ea'	System	24 Nov 2020 02:24:31
User entered 'No (N)'	System	24 Nov 2020 02:24:31

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-11-23T20:24:28', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '3a67cfd1-4b42-40c2-9449-54e5352b88ea' User entered '23 Nov 2020 20:24:28'	System	24 Nov 2020 02:24:31

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2020-11-27T04:47:21', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '70bb4a7a-ebff-4573-b53d-e1dc65773f'	System	27 Nov 2020 10:47:38
User entered 'No (N)'	System	27 Nov 2020 10:47:38

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2020-11-27T04:47:29', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '70bb4a7a-ebff-4573-b53d-e1dc65773f'	System	27 Nov 2020 10:47:38
User entered 'No (N)'	System	27 Nov 2020 10:47:38

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-11-27T04:47:34', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '70bb4a7a-ebff-4573-b53d-e1dc65773f'	System	27 Nov 2020 10:47:38
User entered '27 Nov 2020 04:47:34'	System	27 Nov 2020 10:47:38



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2020-12-04T05:15:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '816a7890-9cca-4594-a106-4bd998175626'	System	04 Dec 2020 11:15:34
User entered 'No (N)'	System	04 Dec 2020 11:15:34

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2020-12-04T05:15:25', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '816a7890-9cca-4594-a106-4bd998175626'	System	04 Dec 2020 11:15:34
User entered 'No (N)'	System	04 Dec 2020 11:15:34

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-12-04T05:15:31', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '816a7890-9cca-4594-a106-4bd998175626'	System	04 Dec 2020 11:15:34
User entered '04 Dec 2020 05:15:31'	System	04 Dec 2020 11:15:34

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2020-12-12T21:39:21', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5a440613-d6d4-445e-b9aa-0a50bc5a485a'	System	13 Dec 2020 03:39:37
User entered 'No (N)'	System	13 Dec 2020 03:39:37

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2020-12-12T21:39:25', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5a440613-d6d4-445e-b9aa-0a50bc5a485a'	System	13 Dec 2020 03:39:37
User entered 'No (N)'	System	13 Dec 2020 03:39:37

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-12-12T21:39:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5a440613-d6d4-445e-b9aa-0a50bc5a485a' User entered '12 Dec 2020 21:39:30'	System	13 Dec 2020 03:39:37
	System	13 Dec 2020 03:39:37

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2020-12-18T10:21:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04853ce0-376c-4429-a48f-c07fd2619db7'	System	18 Dec 2020 16:21:47
User entered 'No (N)'	System	18 Dec 2020 16:21:47



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2020-12-18T10:21:39', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04853ce0-376c-4429-a48f-c07fd2619db7'	System	18 Dec 2020 16:21:47
User entered 'No (N)'	System	18 Dec 2020 16:21:47

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-12-18T10:21:43', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '04853ce0-376c-4429-a48f-c07fd2619db7'	System	18 Dec 2020 16:21:47
User entered '18 Dec 2020 10:21:43'	System	18 Dec 2020 16:21:47

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2020-12-28T12:58:17', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'f1e062d6-dd21-4286-b14c-51b5fc805a63'	System	28 Dec 2020 18:58:30
User entered 'No (N)'	System	28 Dec 2020 18:58:30

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2020-12-28T12:58:20', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'f1e062d6-dd21-4286-b14c-51b5fc805a63'	System	28 Dec 2020 18:58:30
User entered 'No (N)'	System	28 Dec 2020 18:58:30

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2020-12-28T12:58:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'f1e062d6-dd21-4286-b14c-51b5fc805a63'	System	28 Dec 2020 18:58:30
User entered '28 Dec 2020 12:58:24'	System	28 Dec 2020 18:58:30



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-01-01T00:02:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'aa1f9ec8-7f37-430b-b835-11c5772653d9'	System	01 Jan 2021 06:02:35
User entered 'No (N)'	System	01 Jan 2021 06:02:35

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-01-01T00:02:22', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'aa1f9ec8-7f37-430b-b835-11c5772653d9'	System	01 Jan 2021 06:02:35
User entered 'No (N)'	System	01 Jan 2021 06:02:35

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-01-01T00:02:27', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'aa1f9ec8-7f37-430b-b835-11c5772653d9' User entered '01 Jan 2021 00:02:27'	System	01 Jan 2021 06:02:35

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-01-08T08:54:35', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1cb8cd7c-9489-4429-8179-5f6e82e007d3'	System	08 Jan 2021 14:54:51
User entered 'No (N)'	System	08 Jan 2021 14:54:51

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-01-08T08:54:38', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1cb8cd7c-9489-4429-8179-5f6e82e007d3'	System	08 Jan 2021 14:54:51
User entered 'No (N)'	System	08 Jan 2021 14:54:51

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-01-08T08:54:46', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '1cb8cd7c-9489-4429-8179-5f6e82e007d3'	System	08 Jan 2021 14:54:51
User entered '08 Jan 2021 08:54:46'	System	08 Jan 2021 14:54:51

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-01-15T06:19:03', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5a26add5-f54a-4fc2-aca6-2bd8358353b3'	System	15 Jan 2021 12:19:13
User entered 'No (N)'	System	15 Jan 2021 12:19:13



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-01-15T06:19:05', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5a26add5-f54a-4fc2-aca6-2bd8358353b3'	System	15 Jan 2021 12:19:13
User entered 'No (N)'	System	15 Jan 2021 12:19:13

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-01-15T06:19:10', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5a26add5-f54a-4fc2-aca6-2bd8358353b3' User entered '15 Jan 2021 06:19:10'	System	15 Jan 2021 12:19:13

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-01-22T06:05:14', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7db6f34e-6fe9-4954-8656-3f70544f3992'	System	22 Jan 2021 12:05:30
User entered 'No (N)'	System	22 Jan 2021 12:05:30

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-01-22T06:05:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7db6f34e-6fe9-4954-8656-3f70544f3992'	System	22 Jan 2021 12:05:30
User entered 'No (N)'	System	22 Jan 2021 12:05:30

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-01-22T06:05:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '7db6f34e-6fe9-4954-8656-3f70544f3992'	System	22 Jan 2021 12:05:30
User entered '22 Jan 2021 06:05:24'	System	22 Jan 2021 12:05:30



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-02-02T14:18:40', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b98c8cd6-7038-4b85-b58e-23d5cdb534c5'	System	03 Feb 2021 20:42:42
User entered 'No (N)'	System	03 Feb 2021 20:42:42

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-02-02T14:18:43', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b98c8cd6-7038-4b85-b58e-23d5cdb534c5'	System	03 Feb 2021 20:42:42
User entered 'No (N)'	System	03 Feb 2021 20:42:42

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-02-02T14:18:49', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b98c8cd6-7038-4b85-b58e-23d5cdb534c5'	System	03 Feb 2021 20:42:42
User entered '02 Feb 2021 14:18:49'	System	03 Feb 2021 20:42:42

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-02-05T13:38:19', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b1797391-9818-48f9-af09-9103e34aa178'	System	05 Feb 2021 19:38:31
User entered 'No (N)'	System	05 Feb 2021 19:38:31

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-02-05T13:38:24', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b1797391-9818-48f9-af09-9103e34aa178'	System	05 Feb 2021 19:38:31
User entered 'No (N)'	System	05 Feb 2021 19:38:31

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-02-05T13:38:27', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'b1797391-9818-48f9-af09-9103e34aa178'	System	05 Feb 2021 19:38:31
User entered '05 Feb 2021 13:38:27'	System	05 Feb 2021 19:38:31

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-02-12T19:52:27', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c7d32cde-44bf-4c7b-b957-8ed7fe134dd0'	System	13 Feb 2021 01:52:38
User entered 'No (N)'	System	13 Feb 2021 01:52:38



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-02-12T19:52:30', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c7d32cde-44bf-4c7b-b957-8ed7fe134dd0'	System	13 Feb 2021 01:52:38
User entered 'No (N)'	System	13 Feb 2021 01:52:38

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-02-12T19:52:32', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'c7d32cde-44bf-4c7b-b957-8ed7fe134dd0'	System	13 Feb 2021 01:52:38
User entered '12 Feb 2021 19:52:32'	System	13 Feb 2021 01:52:38

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-02-19T05:21:38', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'dd9e07a1-e79d-44d6-8592-b661a53ea176'	System	19 Feb 2021 11:21:53
User entered 'No (N)'	System	19 Feb 2021 11:21:53

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-02-19T05:21:41', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'dd9e07a1-e79d-44d6-8592-b661a53ea176'	System	19 Feb 2021 11:21:53
User entered 'No (N)'	System	19 Feb 2021 11:21:53

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-02-19T05:21:50', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'dd9e07a1-e79d-44d6-8592-b661a53ea176'	System	19 Feb 2021 11:21:53
User entered '19 Feb 2021 05:21:50'	System	19 Feb 2021 11:21:53



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-02-26T07:09:04-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '99431498-dcf1-442f-a281-aa5c35d08ba8' User entered 'No (N)'	System	26 Feb 2021 13:09:13
	System	26 Feb 2021 13:09:13

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-02-26T07:09:06-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '99431498-dcf1-442f-a281-aa5c35d08ba8' User entered 'No (N)'	System	26 Feb 2021 13:09:13

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-02-26T07:09:09-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '99431498-dcf1-442f-a281-aa5c35d08ba8' User entered '26 Feb 2021 07:09:09'	System	26 Feb 2021 13:09:13
	System	26 Feb 2021 13:09:13

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-03-05T05:59:27-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2e071dae-847f-4a9e-8aee-c3abd9e99381'	System	05 Mar 2021 11:59:38
User entered 'No (N)'	System	05 Mar 2021 11:59:38

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-03-05T05:59:29-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2e071dae-847f-4a9e-8aee-c3abd9e99381'	System	05 Mar 2021 11:59:38
User entered 'No (N)'	System	05 Mar 2021 11:59:38

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-03-05T05:59:33-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '2e071dae-847f-4a9e-8aee-c3abd9e99381' User entered '05 Mar 2021 05:59:33'	System	05 Mar 2021 11:59:38
	System	05 Mar 2021 11:59:38

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-03-12T19:52:07-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'db3c7470-91e4-401d-92f4-3b7e3debca2a'	System	13 Mar 2021 01:52:21
User entered 'No (N)'	System	13 Mar 2021 01:52:21



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-03-12T19:52:11-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'db3c7470-91e4-401d-92f4-3b7e3debca2a'	System	13 Mar 2021 01:52:21
User entered 'No (N)'	System	13 Mar 2021 01:52:21

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-03-12T19:52:14-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'db3c7470-91e4-401d-92f4-3b7e3debca2a' User entered '12 Mar 2021 19:52:14'	System	13 Mar 2021 01:52:21
	System	13 Mar 2021 01:52:21

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-03-19T08:05:38-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6ffe62ac-975c-4ab2-a4d1-c5e457e56643'	System	19 Mar 2021 13:05:54
User entered 'No (N)'	System	19 Mar 2021 13:05:54

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-03-19T08:05:44-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6ffe62ac-975c-4ab2-a4d1-c5e457e56643'	System	19 Mar 2021 13:05:54
User entered 'No (N)'	System	19 Mar 2021 13:05:54

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-03-19T08:05:49-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '6ffe62ac-975c-4ab2-a4d1-c5e457e56643'	System	19 Mar 2021 13:05:54
User entered '19 Mar 2021 08:05:49'	System	19 Mar 2021 13:05:54



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-03-26T06:39:37-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5465bf0b-1dd8-4593-9a32-aa366c3e1813'	System	26 Mar 2021 11:39:53
User entered 'No (N)'	System	26 Mar 2021 11:39:53

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-03-26T06:39:40-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5465bf0b-1dd8-4593-9a32-aa366c3e1813'	System	26 Mar 2021 11:39:53
User entered 'No (N)'	System	26 Mar 2021 11:39:53

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-03-26T06:39:49-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '5465bf0b-1dd8-4593-9a32-aa366c3e1813' User entered '26 Mar 2021 06:39:49'	System	26 Mar 2021 11:39:53
	System	26 Mar 2021 11:39:53

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-04-02T08:23:16-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bdf372e3-6753-4deb-a346-0d87fb8113c1'	System	02 Apr 2021 13:23:27
User entered 'No (N)'	System	02 Apr 2021 13:23:27

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-04-02T08:23:19-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bdf372e3-6753-4deb-a346-0d87fb8113c1'	System	02 Apr 2021 13:23:27
User entered 'No (N)'	System	02 Apr 2021 13:23:27

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-04-02T08:23:23-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bdf372e3-6753-4deb-a346-0d87fb8113c1'	System	02 Apr 2021 13:23:27
User entered '02 Apr 2021 08:23:23'	System	02 Apr 2021 13:23:27

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-04-09T19:31:11-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49bee2f4-50c5-4998-9678-a751c902e1b5' User entered 'No (N)'	System	10 Apr 2021 00:31:23
	System	10 Apr 2021 00:31:23



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-04-09T19:31:15-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49bee2f4-50c5-4998-9678-a751c902e1b5' User entered 'No (N)'	System	10 Apr 2021 00:31:23
	System	10 Apr 2021 00:31:23

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-04-09T19:31:19-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '49bee2f4-50c5-4998-9678-a751c902e1b5' User entered '09 Apr 2021 19:31:19'	System	10 Apr 2021 00:31:23
	System	10 Apr 2021 00:31:23

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-04-16T19:30:38-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fc425f2c-1985-4f05-9292-9e17d53d1b19'	System	17 Apr 2021 00:30:49
User entered 'No (N)'	System	17 Apr 2021 00:30:49

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-04-16T19:30:41-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fc425f2c-1985-4f05-9292-9e17d53d1b19'	System	17 Apr 2021 00:30:49
User entered 'No (N)'	System	17 Apr 2021 00:30:49

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-04-16T19:30:46-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'fc425f2c-1985-4f05-9292-9e17d53d1b19'	System	17 Apr 2021 00:30:49
User entered '16 Apr 2021 19:30:46'	System	17 Apr 2021 00:30:49



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-04-23T17:05:17-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bcf8f55c-3931-4e08-9390-f64269e89dcf' User entered 'No (N)'	System	23 Apr 2021 22:08:28

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-04-23T17:05:19-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bcf8f55c-3931-4e08-9390-f64269e89dcf' User entered 'No (N)'	System	23 Apr 2021 22:08:28

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-04-23T17:05:22-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: 'bcf8f55c-3931-4e08-9390-f64269e89dcf' User entered '23 Apr 2021 17:05:22'	System	23 Apr 2021 22:08:28
	System	23 Apr 2021 22:08:28

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[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 (032659aff6ff0e95)', Time: '2021-04-30T19:32:34-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '194eb595-f529-48cd-888f-a485e608fa54'	System	01 May 2021 00:33:09
User entered 'No (N)'	System	01 May 2021 00:33:09

US3552386

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:43

Have you been exposed to someone with 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 (032659aff6ff0e95)', Time: '2021-04-30T19:32:41-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '194eb595-f529-48cd-888f-a485e608fa54'	System	01 May 2021 00:33:09
User entered 'No (N)'	System	01 May 2021 00:33:09

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-04-30T19:32:56-05:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '194eb595-f529-48cd-888f-a485e608fa54'	System	01 May 2021 00:33:09
User entered '30 Apr 2021 19:32:56'	System	01 May 2021 00:33:09

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:50:02

**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:50:02



**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:50:02

**US3552386**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:16:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:50:02
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:50:02

US3552386

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:16:43**

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 11:35:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-03-03T05:25:01-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '9410379a-572c-4f37-9b53-6087bc51dc99'	System	03 Mar 2021 11:25:08
User entered 'No (N)'	System	03 Mar 2021 11:25:08

**US3552386**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:35:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (032659aff6ff0e95)', Time: '2021-03-03T05:25:05-06:00', User OID: 'PatientReportedOutcome (US3552386)', ODM File OID: '9410379a-572c-4f37-9b53-6087bc51dc99'	System	03 Mar 2021 11:25:08
User entered '03 Mar 2021 05:25:05'	System	03 Mar 2021 11:25:08



US3552386

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Dec 2020 22:01:25

US3552386

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '08 Dec 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	08 Dec 2020 22:19:44
User entered '8 Dec 2020'	Mikayla Frye (b) (4) (b) (4)	08 Dec 2020 22:01:25

US3552386

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	08 Dec 2020 22:01:25

US3552386

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Dec 2020 22:01:25

US3552386

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 18:01:53

US3552386

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 11:14:04
User entered 'l'	System	11 Jan 2021 18:01:53

US3552386

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 18:02:03

US3552386

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '11 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 18:02:03



US3552386

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	11 Jan 2021 18:02:03

US3552386

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4)	11 Jan 2021 18:02:03

US3552386

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:57:51

US3552386

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User entered 'l'	System	10 Feb 2021 20:57:51

US3552386

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:57:58

US3552386

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '10 Feb 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:57:58

US3552386

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:57:58

US3552386

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:57:58



US3552386

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 22:23:56

US3552386

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User entered 'l'	System	11 Feb 2021 22:23:56

US3552386

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:33:40

US3552386

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered '15 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:33:40

US3552386

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4)	15 Mar 2021 16:33:40

US3552386

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Dublin (b) (4)	15 Mar 2021 16:33:40

US3552386

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:33:45

**US3552386**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:59
User entered 'l'	System	15 Mar 2021 16:33:45



US3552386

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:25:47

US3552386

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '09 Apr 2021'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:25:47

US3552386

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'Clinic (Clinic)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:25:47

**US3552386**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:43**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	09 Apr 2021 21:25:47

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '09 Apr 2021'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '16:03'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08

**US3552386**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 16:03'	System	09 Apr 2021 21:26:08



US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '98.1' F	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'Oral (Oral)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '77'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08

**US3552386**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:43**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '16'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '124'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08



**US3552386**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '82'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:08

**US3552386**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 21:26:08

US3552386

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:15

US3552386

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '09 Apr 2021'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:15

US3552386

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:24

US3552386

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '09 Apr 2021'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:24

US3552386

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '16:16'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:24



**US3552386**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:16:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 16:16'	System	09 Apr 2021 21:26:24

US3552386

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:26:28

**US3552386**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 21:26:28

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:41:03

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:41:03

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:41:03

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 19:41:03

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:41:19



**US3552386**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:16:43**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:59:56

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:59:56

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Placebo (Placebo)'	Stanley Doublin (b) (4) (b) (4)	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 14:33:52
User entered 'Placebo (Placebo)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 14:33:52
User entered 'Placebo (Placebo)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:41:19



US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'I'	System	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:16:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'I'	System	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered empty.	System	14 Jan 2021 19:42:01
DataPoint set to visible.	System	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered empty.	System	14 Jan 2021 19:42:01
DataPoint set to visible.	System	14 Jan 2021 19:41:19



US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '11:15'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered '14 Jan 2021 11:15'	System	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '98.5' F	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01



US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '69'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'bpm'	System	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '14'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'breaths/min'	System	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '132'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'mmHg'	System	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '84'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'mmHg'	System	14 Jan 2021 19:42:01



US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:01

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered empty.	System	14 Jan 2021 19:42:01
DataPoint set to visible.	System	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '12:10'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered '14 Jan 2021 12:10'	System	14 Jan 2021 19:42:30



US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '98.8' F	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '69'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'bpm'	System	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '12'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'breaths/min'	System	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '134'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30



US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'mmHg'	System	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '87'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'mmHg'	System	14 Jan 2021 19:42:30

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:39

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:39

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:52

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:52

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:52



US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'mRNA-1273'	System	14 Jan 2021 19:42:52
DataPoint set to visible.	System	14 Jan 2021 19:41:19

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:52

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '11:35'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:52

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered '14 Jan 2021 11:35'	System	14 Jan 2021 19:42:52

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:42:52

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'ONCE'	System	14 Jan 2021 19:42:52

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 19:42:52

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:43:05



US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:43:05

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered '11:02'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:43:05

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered '14 Jan 2021 11:02'	System	14 Jan 2021 19:43:05

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:43:14

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:43:14

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '10:55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	14 Jan 2021 19:43:14

**US3552386**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:16:43**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered '14 Jan 2021 10:55'	System	14 Jan 2021 19:43:14

US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	25 Jan 2021 18:39:48



US3552386

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:49
User entered 'I'	System	25 Jan 2021 18:39:48

US3552386

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Jan 2021 18:39:57

US3552386

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '22 Jan 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	25 Jan 2021 18:39:57

US3552386

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Heather Douds (b) (4)	25 Jan 2021 18:39:57

US3552386

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	25 Jan 2021 18:39:57

US3552386

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:35:55

US3552386

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User entered 'l'	System	09 Feb 2021 13:35:55

US3552386

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:25:14
User entered 'I'	System	09 Feb 2021 13:35:55
DataPoint set to visible.	System	09 Feb 2021 13:35:55



US3552386

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:12

US3552386

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '08 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:12

US3552386

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:12

US3552386

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'OLD29'	System	09 Feb 2021 13:36:12

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	26 Feb 2021 03:30:28
User entered '08 Feb 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	22 Feb 2021 21:22:57
User entered '8 Feb 2021'	Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	22 Feb 2021 21:22:57
User entered '13:50' reason for change: Data Entry Error	System	22 Feb 2021 21:22:57
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	Cassandra Zehenny (b) (4)	09 Feb 2021 13:37:59
User entered '14:50'	System	09 Feb 2021 13:36:40
	Stanley Dublin (b) (4)	
	(b) (4)	



**US3552386**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '08 Feb 2021 13:50'	System	22 Feb 2021 21:22:57
User entered '8 Feb 2021 14:50'	System	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '98.4' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '80'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

**US3552386**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'bpm'	System	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'breaths/min'	System	09 Feb 2021 13:36:40



US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '164'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'mmHg'	System	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '94'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'mmHg'	System	09 Feb 2021 13:36:40

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '08 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '14:50'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32



US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '08 Feb 2021 14:50'	System	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '98.9' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '90'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'bpm'	System	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'breaths/min'	System	09 Feb 2021 13:37:32



US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '128'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'mmHg'	System	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:28
User entered '89'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'mmHg'	System	09 Feb 2021 13:37:32

US3552386

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:43

US3552386

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '08 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:43

US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:59

US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:59



US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:59

US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'mRNA-1273'	System	09 Feb 2021 13:37:59
DataPoint set to visible.	System	09 Feb 2021 13:35:55

US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '08 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:59

US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '14:20'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:59

US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '08 Feb 2021 14:20'	System	09 Feb 2021 13:37:59

US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Feb 2021 13:37:59

US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'ONCE'	System	09 Feb 2021 13:37:59

US3552386

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 13:37:59



US3552386

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	11 Feb 2021 22:23:45

US3552386

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'l'	System	11 Feb 2021 22:23:45

US3552386

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:39:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 17:47:52

US3552386

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:39:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '16 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 17:47:52

US3552386

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:39:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 17:47:52

US3552386

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:39:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 17:47:52

US3552386

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:39:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 17:49:09

**US3552386**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:16:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:39:44
User entered 'l'	System	17 Feb 2021 17:49:09



US3552386

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:01

US3552386

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:24
User entered '12 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:01

US3552386

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:24
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Mar 2021 12:29:01

**US3552386**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:16:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User entered 'OLD57'	System	15 Mar 2021 12:29:01

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:08

**US3552386**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User entered empty.	System	15 Mar 2021 12:29:08



US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:08

**US3552386**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:16:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User entered empty.	System	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User entered empty.	System	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:08



US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User entered empty.	System	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:29
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User entered empty.	System	15 Mar 2021 12:29:08

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46

US3552386

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46

US3552386

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:18

US3552386

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:24
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:18

US3552386

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:33



US3552386

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:24
User entered '12 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:33

US3552386

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:39:24
User entered '13:56'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 12:29:33

**US3552386**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:16:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:46
User entered '12 Mar 2021 13:56'	System	15 Mar 2021 12:29:33

US3552386

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:16:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:33
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:32:53
Signature has been broken.	Cassandra Zehenny (b) (4)	09 Apr 2021 21:26:37
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4)	09 Apr 2021 21:26:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
	(b) (4)	
User entered 'No (N)'	Cassandra Zehenny (b) (4)	17 Feb 2021 20:18:25
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:04
User entered	System	12 Apr 2021 18:41:44
'USA-US089-2021-mRNA-1273-P301000009'		
User entered 'New'	(b) (4), (b) (6)	12 Apr 2021 18:41:44

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:09
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal tear, LLT: Retinal tear - version MedDRA\23.0.	Coder Import (b) (4)	11 Apr 2021 19:30:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Apr 2021 19:30:35
Data point term sent to Coder	System	09 Apr 2021 21:28:43
User entered 'Right eye retinal tear'	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 21:27:49
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:27:49



US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:27:49

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 21:44:03
User closed query 'Per source, start date 29Mar2021. Please reconcile. ' (Site from CRA).		13 Apr 2021 21:43:50
Query 'Per source, start date 29Mar2021. Please reconcile. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	12 Apr 2021 21:52:22
User entered '29 Mar 2021' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	12 Apr 2021 21:52:16
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:12
DataPoint Verified.		12 Apr 2021 20:29:09
User opened query 'Per source, start date 29Mar2021. Please reconcile. ' (Site from CRA).		12 Apr 2021 20:05:58
User entered '31 Mar 2021'	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

**US3552386**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered empty.	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

**US3552386**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:16:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 21:27:49

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 12:17:44
DataPoint Verified.	sharon frey (b) (4) (b) (4)	16 Apr 2021 18:03:26
User entered 'Yes (Y)'	(b) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4)	12 Apr 2021 20:29:09 09 Apr 2021 21:27:49

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 21:27:49
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 21:27:49
	Cassandra Zehenny (b) (4)	
	(b) (4)	

**US3552386**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:16:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 21:27:49



US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered 'Grade 4 (Grade 4)'	Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:27:49

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:09
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	09 Apr 2021 21:29:56
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	09 Apr 2021 21:27:49
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

**US3552386**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 21:27:49
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
User entered '0'	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 07:10:14
		21 Apr 2021 03:28:25
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant). ' (Site from Safety).		20 Apr 2021 19:15:24
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'updated' (Site from System).	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:47
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant). ' answered with 'updated' (Site from Safety).	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:42
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). DataPoint Un-verified.	System	19 Apr 2021 16:48:27
	Cassandra Zehenny (b) (4)	19 Apr 2021 16:48:27
Signature has been broken.	Cassandra Zehenny (b) (4)	19 Apr 2021 16:48:27
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	19 Apr 2021 16:48:27
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant). ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:18:16
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:29:09

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed 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	09 Apr 2021 21:30:18
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.' answered by data change (Site from System).		09 Apr 2021 21:30:18
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	09 Apr 2021 21:29:56
User entered '1' reason for change: New Information	Cassandra Zehenny (b) (4)	09 Apr 2021 21:29:56
User entered '0'	(b) (4) Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:28:33
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:34
User entered empty; reason for change New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:34
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered '31 Mar 2021' reason for change: New Information	Cassandra Zehenny (b) (4)	09 Apr 2021 21:29:56
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:28:35
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:34
Signature has been broken.	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:34
User entered empty; reason for change New Information	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:34
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:45:19
User closed query 'Please verify the discharge date. Subject was admitted at night 12:32 am on 31Mer2021,. Procedure was done in the morning on the same day, 31Mar2021, not 01Apr2021. Patient was released was released after procedure.. ' (Site from CRA).		13 Apr 2021 21:45:07
Query 'Please verify the discharge date. Subject was admitted at night 12:32 am on 31Mer2021,. Procedure was done in the morning on the same day, 31Mar2021, not 01Apr2021. Patient was released was released after procedure.. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	12 Apr 2021 21:52:28
User entered '31 Mar 2021' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Apr 2021 21:52:16
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 20:29:15
DataPoint Verified.		12 Apr 2021 20:29:09
User opened query 'Please verify the discharge date. Subject was admitted at night 12:32 am on 31Mer2021,. Procedure was done in the morning on the same day, 31Mar2021, not 01Apr2021. Patient was released was released after procedure.. ' (Site from CRA).		12 Apr 2021 20:28:51
User entered '01 Apr 2021' reason for change: New Information	Cassandra Zehenny (b) (4)	09 Apr 2021 21:29:56
User entered empty.	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49



US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:28:37
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Apr 2021 16:55:00
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Apr 2021 16:55:00
User entered empty; reason for change Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Apr 2021 16:55:00
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Apr 2021 21:30:18
	(b) (4)	
User entered empty.	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered empty.	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
User entered '0'	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:27:49

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:28:40
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Apr 2021 16:48:27
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Apr 2021 16:48:27
User entered '1' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered '0'	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:27:49



US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered '0'	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
User entered '0'	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
User entered 'l'	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:18:31
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:29:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	09 Apr 2021 21:27:49

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:29:09
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 21:27:49
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:28:49
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).		20 Apr 2021 19:15:30
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:34
Signature has been broken.	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:34
	(b) (4)	
User entered 'SUBJECT WENT TO URGENT CARE FOR NEW FLOATER IN RIGHT EYE, IMMEDIATELY SENT TO HOSPITAL FOR SUSPECTED RETINAL TEAR. WAS NOT ADMITTED TO HOSPITAL, WAITED IN ED BEFORE RETINAL TEAR REPAIR SURGERY EARLY MORNING OF 31MAR. MEDICAL RECORDS REQUESTED ON 09APR, WILL UPDATE ONCE OBTAINED. UPDATE 4/12 - REPAIR ON 31Mar WAS A LASER RETINOPEXY; NO OCULAR MEDS PRESCRIBED ASIDE FROM THOSE GIVEN FOR EXAM IN ED. WILL SEND MEDICAL RECORDS TO MEDICAL MONITOR.' reason for change: New Information	Cassandra Zehenny (b) (4)	19 Apr 2021 16:54:34
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'No COVID testing done' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:18:41
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:29:09

US3552386

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:43

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WENT TO URGENT CARE FOR NEW FLOATER IN RIGHT EYE, IMMEDIATELY SENT TO HOSPITAL FOR SUSPECTED RETINAL TEAR. WAS NOT ADMITTED TO HOSPITAL BUT HAD TO WAIT IN ED OVERNIGHT DUE BEFORE RETINAL TEAR REPAIR SURGERY EARLY MORNING OF 01APR. MEDICAL RECORDS REQUESTED ON 09APR, WILL UPDATE ONCE OBTAINED. Update 4/12 - repair on 4/1 was a laser retinoplexy; no ocular meds prescribed aside from those given for exam in ED. Will send medical records to medical monitor.' reason for change: New Information	Heather Douds (b) (4)	12 Apr 2021 15:05:45
User entered 'Subject went to urgent care for new floater in right eye, immediately sent to hospital for suspected retinal tear. was not admitted to hospital but had to wait in ED overnight due before retinal tear repair surgery early morning of 01APR. medical records requested on 09APR, will update once obtained.' reason for change: New Information	Cassandra Zehenny (b) (4)	09 Apr 2021 21:29:56
User entered empty.	Cassandra Zehenny (b) (4)	09 Apr 2021 21:27:49

**US3552386**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 21:27:49



**US3552386**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 21:27:49

**US3552386**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 21:30:18

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:16:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:33
DataPoint Verified.		21 Apr 2021 03:29:16
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:27:57

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: CARBOXAMIDE DERIVATIVES, PRODUCT: OXCARBAZEPINE, PRODUCTSYNONYM: TRILEPTAL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:45:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:45:51
Data point term sent to Coder	System	10 Sep 2020 14:29:30
User entered 'trileptal'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'seizures'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:13:53
Signature has been broken.	(b) (4) Heather Douds (b) (4)	01 Apr 2021 16:18:33
User signature succeeded.	(b) (4) sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '300'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'mg (mg)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'twice daily (BID)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2010'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 14:29:14

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 14:29:14

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:32:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:32:57
Data point term sent to Coder	System	10 Sep 2020 14:30:31
User entered 'flonase'	Mikayla Frye (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'seasonal allergies'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '2'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Other (OTHER)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'spray'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Nasal (NASAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 1990'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 14:29:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 14:29:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:32:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:32:58
Data point term sent to Coder	System	10 Sep 2020 14:30:32
User entered 'allegra'	Mikayla Frye (b) (4)	10 Sep 2020 14:30:26



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'seasonal allergies'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
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. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 10:33:22
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. ' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	09 Oct 2020 15:06:24
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. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 01:06:02
User entered 'I'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'tablet (TABLET)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2017'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 14:30:26

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 14:30:26



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 14:30:26

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:33:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:33:11
Data point term sent to Coder	System	10 Sep 2020 14:31:33
User entered 'multivitamin'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Mikayla Frye (b) (4)	11 Nov 2020 17:01:34
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'health promotion'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'I'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'tablet (TABLET)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 2019'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:17



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 14:31:17

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 14:31:17

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:47:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:47:28
Data point term sent to Coder	System	28 Oct 2020 14:47:38
Coding entries removed.	Cassandra Zehenny (b) (4)	28 Oct 2020 14:47:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 16:19:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 16:19:48
Data point term sent to Coder	System	10 Sep 2020 16:18:10
Coding entries removed.	Heather Douds (b) (4)	10 Sep 2020 16:17:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:33:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:33:38
Data point term sent to Coder	System	10 Sep 2020 14:32:38
User entered 'tylenol'	Mikayla Frye (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of myalgia. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:52:13
Query 'Per DM CLR: Please update the indication to reflect the location and type of myalgia. Review and update indication and ensure to update MH eCRF as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	28 Oct 2020 14:47:37
User entered 'generalized MYALGIA' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	28 Oct 2020 14:47:31
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of myalgia. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:07:11
Query 'Per DM CLR: Please update the indication to reflect the location and type of myalgia. Review and update indication and ensure to update MH eCRF as appropriate.' canceled (Site from DM).		09 Oct 2020 01:06:29
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of myalgia. Review and update indication and ensure to update MH eCRF as appropriate.' (Site from DM).		09 Oct 2020 01:06:22
User entered 'myalgia' reason for change: Data Entry Error	Heather Douds (b) (4)	10 Sep 2020 16:17:57
User entered 'muscle soreness'	Mikayla Frye (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
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. ' (Site from DM).	(b) (4)	
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. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 08:54:57
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. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	09 Oct 2020 15:07:08
User entered '1000' reason for change: Per Query Resolution	(b) (4)	
User entered '1000' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	09 Oct 2020 15:06:46
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. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 01:07:02
User entered '2'	Mikayla Frye (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	09 Oct 2020 15:06:46
User entered 'tablet (TABLET)'	(b) (4)	
	Mikayla Frye (b) (4)	10 Sep 2020 14:31:53
	(b) (4)	



US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'as needed (PRN)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'un UNK 1980'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53



US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '06 Sep 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:31:53

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User entered empty.	System	10 Sep 2020 14:31:53

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User entered empty.	System	10 Sep 2020 14:31:53

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:09
User entered empty.	System	10 Sep 2020 14:31:53

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:44:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:44:46
Data point term sent to Coder	System	10 Sep 2020 14:32:39
User entered 'Vitamin D + Calcium'	Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Mikayla Frye (b) (4)	11 Nov 2020 17:01:43
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'health promotion'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'I'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'tablet (TABLET)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'once daily (QD)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Oral (ORAL)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '01 Oct 2018'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 14:32:31

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 14:32:31

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 17:48:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 17:48:01
Data point term sent to Coder	System	30 Sep 2020 17:46:41
Coding entries removed.	Stanley Doublin (b) (4)	30 Sep 2020 17:46:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 17:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 17:44:49
Data point term sent to Coder	System	30 Sep 2020 17:43:35
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	30 Sep 2020 17:42:55



US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Prophylaxis' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	30 Sep 2020 17:46:23
User entered 'flu prevention'	(b) (4)	
	Stanley Dublin (b) (4)	30 Sep 2020 17:42:55
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Other (OTHER)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:16:43**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'injection'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'once (ONCE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55



US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '24 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered '24 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:42:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:16:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User entered empty.	System	30 Sep 2020 17:42:55

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User entered empty.	System	30 Sep 2020 17:42:55



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:41:11
User entered empty.	System	30 Sep 2020 17:42:55

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:38
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: MYDRIATICS AND CYCLOPLEGICS, ATC: ANTICHOLINERGICS, PRODUCT: TROPICAMIDE, PRODUCTSYNONYM: MYDRIACYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:52:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:52:10
Data point term sent to Coder	System	12 Apr 2021 15:01:24
User entered 'mydriacyl 1.0%'	Heather Douds (b) (4) (b) (4)	12 Apr 2021 15:00:40
DataPoint activated with code reason code Data required.	Heather Douds (b) (4) (b) (4)	12 Apr 2021 14:59:21
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4) (b) (4)	01 Apr 2021 16:18:33

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:38
User entered 'No (N)'	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:38
User entered 'retinal tear R eye'	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:38
User entered 'I'	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:38
User entered 'Other (OTHER)'	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:38
User entered 'drop'	(b) (4), (b) (6)	12 Apr 2021 15:00:40
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	01 Apr 2021 16:18:33
	Heather Douds (b) (4)	
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:38
User entered 'once (ONCE)'	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	



US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:38
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 18:55:38
	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	12 Apr 2021 15:00:40
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	12 Apr 2021 14:59:21
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	01 Apr 2021 16:18:33

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:38
	(b) (4), (b) (6)	
User entered 'Intraocular (INTRAOCULAR)'	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:38
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 18:55:38
	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	12 Apr 2021 15:00:40
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	12 Apr 2021 14:59:21
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	01 Apr 2021 16:18:33

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:38
User entered '31 Mar 2021'	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:38
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 18:55:38
	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	12 Apr 2021 15:00:40
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	12 Apr 2021 14:59:21
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	01 Apr 2021 16:18:33

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:38
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 18:55:38
	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	12 Apr 2021 15:00:40
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	12 Apr 2021 14:59:21
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	01 Apr 2021 16:18:33

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:38
User entered '31 Mar 2021'	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:38
User entered 'No (N)'	Heather Douds (b) (4)	12 Apr 2021 15:00:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33
	(b) (4)	



US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:16:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:00:40
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:00:40
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:00:40
DataPoint activated with code reason code Data required.	Heather Douds (b) (4)	12 Apr 2021 14:59:21
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	01 Apr 2021 16:18:33

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:42
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: SYMPATHOMIMETICS IN GLAUCOMA THERAPY, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:38:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:38:43
Data point term sent to Coder	System	12 Apr 2021 15:01:24
User entered '2.5% epinephrine'	Heather Douds (b) (4) (b) (4)	12 Apr 2021 15:01:20

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 18:55:42
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered 'retinal tear R eye'	(b) (4), (b) (6)	15 Apr 2021 18:55:42
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered 'l'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Apr 2021 18:55:42
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	



US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered 'drop'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered 'once (ONCE)'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:16:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:42
User entered empty.	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:16:43**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:42
User entered 'Intraocular (INTRAOCULAR)'	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:16:43**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered empty.	(b) (4), (b) (6)	
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 18:55:42
User entered '31 Mar 2021'	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:16:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered '0'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered 'No (N)'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	



US3552386

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:16:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered '31 Mar 2021'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:16:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	15 Apr 2021 18:55:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 18:55:42
	Heather Douds (b) (4)	12 Apr 2021 15:01:20
	(b) (4)	

**US3552386**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:16:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:01:20

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:01:20

US3552386

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:16:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 15:01:20

US3552386

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:16:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:33
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:33:01
Signature has been broken.	Cassandra Zehenny (b) (4)	09 Apr 2021 21:30:27
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4)	09 Apr 2021 21:30:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:03:31
User entered 'No (N)'	(b) (4)	17 Feb 2021 20:18:31
	Cassandra Zehenny (b) (4)	

US3552386

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 21:50:30
User closed query 'Per PCP notes, procedure performed early morning of 31Mar2021. Please reconcile the date. ' (Site from CRA).		13 Apr 2021 21:50:18
Query 'Per PCP notes, procedure performed early morning of 31Mar2021. Please reconcile the date. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	12 Apr 2021 21:51:26
User entered '31 Mar 2021' reason for change: Data Entry Error	(b) (4)	12 Apr 2021 21:51:22
User opened query 'Per PCP notes, procedure performed early morning of 31Mar2021. Please reconcile the date. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:20:47
DataPoint Un-verified.		12 Apr 2021 20:20:04
DataPoint Verified.		12 Apr 2021 20:19:56
User entered '01 Apr 2021'	Cassandra Zehenny (b) (4)	09 Apr 2021 21:30:45

US3552386

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:19:56
User entered 'Laser retinoplexy R eye' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Apr 2021 15:02:05
User entered 'right eye retinal tear repair'	(b) (4)	
	Cassandra Zehenny (b) (4)	09 Apr 2021 21:30:45
	(b) (4)	



US3552386

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:19:56
User entered 'Adverse Event (AE)'	Cassandra Zehenny (b) (4)	09 Apr 2021 21:30:45
	(b) (4)	

US3552386

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:19:56
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 21:30:45
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:54
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:49
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'USA-US089-2021-MRNA-1273-P301000009'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:48
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'No (N)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44



**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:50
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'Yes (Y)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.		12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'sharon'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'frey'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'MO'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:15:09
DataPoint Verified.		12 Apr 2021 20:32:45
User entered 'US'	System	12 Apr 2021 18:42:28

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 19:16:13
User entered '3'	System	13 Apr 2021 14:50:02
User entered '2'	System	13 Apr 2021 14:15:20
User entered '1'	System	12 Apr 2021 18:42:28

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:54
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:49
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'USA-US089-2021-MRNA-1273-P301000009'	System	12 Apr 2021 18:41:44



**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:48
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'No (N)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:50
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'Yes (Y)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.		12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'sharon'	System	12 Apr 2021 18:41:44



US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'frey'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'MO'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:15:09
DataPoint Verified.		12 Apr 2021 20:32:45
User entered 'US'	System	12 Apr 2021 18:42:28

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 19:16:13
User entered '3'	System	13 Apr 2021 14:50:02
User entered '2'	System	13 Apr 2021 14:15:20
User entered '1'	System	12 Apr 2021 18:42:28

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:16:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
	(b) (4), (b) (6)	
User entered '12/Apr/2021 14:42'	System	12 Apr 2021 18:42:28

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:16:43

**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)	16 Apr 2021 18:03:26
Reviewed for Safety.	(b) (4)	13 Apr 2021 14:15:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
User entered 'l'		12 Apr 2021 18:42:28

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:54
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:49
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'USA-US089-2021-MRNA-1273-P301000009'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44



**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:48
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'No (N)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:50
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'Yes (Y)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.		12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'sharon'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'frey'	System	12 Apr 2021 18:41:44



**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'MO'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 14:15:09
DataPoint Verified.		12 Apr 2021 20:32:45
User entered 'US'	System	12 Apr 2021 18:42:28

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 19:16:13
User entered '3'	System	13 Apr 2021 14:50:02
User entered '2'	System	13 Apr 2021 14:15:20
User entered '1'	System	12 Apr 2021 18:42:28

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:16:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
User entered '13/Apr/2021 09:15'	(b) (4) System	13 Apr 2021 14:15:20

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:16:43

**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)	16 Apr 2021 18:03:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:49:53
User entered 'I'		13 Apr 2021 14:15:20

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:54
Un-reviewed for Safety.		20 Apr 2021 19:15:49
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.		12 Apr 2021 18:42:21
User entered	System	12 Apr 2021 18:41:44
'USA-US089-2021-MRNA-1273-P301000009'		

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44



US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:48
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'No (N)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:50
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'Yes (Y)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.		12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'sharon'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'frey'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'MO'	System	12 Apr 2021 18:41:44



US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
Reviewed for Safety.	(b) (4)	13 Apr 2021 14:15:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
User entered 'US'	System	12 Apr 2021 18:42:28

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 19:16:13
User entered '3'	System	13 Apr 2021 14:50:02
User entered '2'	System	13 Apr 2021 14:15:20
User entered '1'	System	12 Apr 2021 18:42:28

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 08:16:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	14 Apr 2021 15:52:08
User entered '13/Apr/2021 09:50'	(b) (4), (b) (6)	13 Apr 2021 14:50:02
	System	

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:16:43

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:46
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	14 Apr 2021 15:52:08
User entered 'l'	(b) (4), (b) (6)	13 Apr 2021 14:50:02

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:54
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 19:15:49
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'USA-US089-2021-MRNA-1273-P301000009'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44



US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:48
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'No (N)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'Yes (Y)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:50
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 19:15:46
Un-reviewed for Safety.	System	19 Apr 2021 16:48:27
DataPoint Un-verified.	System	19 Apr 2021 16:48:27
Signature has been broken.	System	19 Apr 2021 16:48:27
User entered 'Yes (Y)'	System	19 Apr 2021 16:48:27
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:32:45
Reviewed for Safety.		12 Apr 2021 18:42:21
User entered 'No (N)'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'sharon'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'frey'	System	12 Apr 2021 18:41:44

**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
DataPoint Verified.	(b) (4)	12 Apr 2021 20:32:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:42:21
User entered 'MO'	System	12 Apr 2021 18:41:44

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:15:09
DataPoint Verified.		12 Apr 2021 20:32:45
User entered 'US'	System	12 Apr 2021 18:42:28



**US3552386**

**Folder: SAE USA-US089-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:16:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 19:16:13
User entered '3'	System	13 Apr 2021 14:50:02
User entered '2'	System	13 Apr 2021 14:15:20
User entered '1'	System	12 Apr 2021 18:42:28

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:16:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:57
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
User entered '20/Apr/2021 15:16'	(b) (4) System	20 Apr 2021 19:16:13

US3552386

Folder: SAE USA-US089-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:16:43

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:29:57
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:41:04
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 19:16:13